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ANALYSIS OF POWER SUPPLY METHODS FOR WIRELESS
BIOMEDICAL SENSORS AND FUTURE DEVELOPMENT PROSPECTS

Master of Science Thesis

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ABSTRACT

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Implantable biomedical devices have been designed to provide monitoring and diagnosis of the physical information in human bodies. The population is ageing and there are many increasing chronic diseases at all ages all around the world, that's why modern methods of diagnosis and monitoring chronic diseases play a vital role in medicine and human health. Biomedical wearable devices and implantable devices are in high demand due to their wider applications. Wireless powering methods can improve the way a patient's health can be monitored and also help patients who are living far from the hospitals.

The current thesis has been focused on the analysis of wireless powering methods for implantable biomedical sensors, their advantages and drawbacks, requirements of different approaches as well as current and future challenges. In order to implement a wireless powering method, developers have to establish quality management systems in the designing phase, to implement safe and effective devices, and meet the requirements of regulatory authorities. These wireless powering methods and devices can improve quality of life to the patients and extend their lives.

However, one of the significant challenges is the power supply, because it is vital to provide sufficient power and to maintain it on the same level along the whole time when the system is operational. Modern wireless IMDs require a stable and continuous power consumption; that's why this problem becomes significant.

PREFACE

This thesis was made as a part of the requirement for completing the Master's in Wireless Communications.

I express my deep gratitude to my supervisor, Professor Leena Ukkonen, who patiently supervised the thesis and her support, comments and guidance has led the work to successful conclusion. Indeed, without her support, this work would not have been possible. It was a long and very exciting work: I really enjoyed this period. I started my thesis in August 2017. Later in May, I was offered an internship from a London based start-up company, I was working there for one year and completed it in June 2018. Within this period, I was working and writing the thesis at the same time.

This thesis was performed at the Department of Electronics and Communication Engineering in the Tampere University of Technology, Finland. First of all, I decided to divide my thesis into several parts, at the initial stage I tried to identify modern publications and articles from well-respected journals. At the second stage, I compiled all my observations and notes together, and wrote the main part of the thesis. At the third stage, I learned more specific topics such as cybersecurity for IMDs and types of antennas which employ IMDs.

I also want to thank my colleagues and friends at the Tampere University of Technology for their valuable comments, suggestions, encouragement, and support through the process. Special thanks to my parents for their support at every stage of my life.

Tampere, June 09.05.2018

Konstantin Khramtcov

TABLE OF CONTENTS

1. INTRODUCTION	1
1.1 Research Objective.....	2
1.2 Thesis Outline	2
2. SENSOR TECHNOLOGIES	3
2.1 History of implantable biomedical sensors	3
2.2 Sensor characteristics	5
2.2.1 Sensitivity	5
2.2.2 Measurement range.....	6
2.2.3 Precision	6
2.2.4 Accuracy	6
2.2.5 Linearity	6
2.2.6 Hysteresis	7
2.2.7 Resolution.....	7
2.2.8 Response Time	7
2.3 Frequency bands for wireless bio-medical implants	7
2.4 Security of wireless medical devices.....	10
3. MODULATION TECHNIQUES FOR IMDs.....	12
3.1 Principle of ASK modulation technique.....	13
3.1.1 ASK modulation method for implantable biomedical sensors	14
3.2 Principle of PSK modulation technique	15
3.2.1 PSK modulation method for implantable biomedical sensors	15
3.3 Principle of FSK modulation technique	16
3.3.1 FSK modulation method for implantable biomedical sensors	17
4. POWERING METHODS FOR IMPLANTABLE BIOMEDICAL SENSORS	19
4.1 Lithium batteries.....	21
4.2 Nuclear batteries	21
4.3 Piezoelectricity power generators.....	22
4.4 Thermoelectricity.....	26
4.5 Electrostatic generators.....	29
4.6 Electromagnetic harvesters.....	32
4.7 Ultrasonic energy transmission	34
4.8 Photovoltaic infrared power radiation	36
4.9 Inductive coupling	37
4.10 Far Field Communications	40
4.11 Mid-Field Communication	40
4.12 Bio-fuel cells	41
5. CURRENT CHALLENGES AND FUTURE PROSPECTIVE OF IMDs	43
5.1 Power management.....	43
5.2 Biocompatibility	44
5.3 Health issues related to wireless power transfer energy.....	45

5.4 Size of the IMDs.....	46
5.5 Frequency band selection	46
5.6 Antennas	47
5.6.1 Dual-band operation antenna.....	47
5.6.2 Implantable antennas for wireless power transfer	48
5.6.3 Integrated implantable antennas	48
5.7 Security.....	48
5.8 Amplifiers for IMDs.....	50
5.9 Future prospects.....	51
6. CONCLUSIONS	53
BIBLIOGRAPHY	54

LIST OF FIGURES

Figure 1. Examples of biomedical devices. [160]	1
Figure 2. Cardiac before and after the wireless transfer	4
Figure 3. Timeline evolution of IMDs.....	4
Figure 4. Sensors sensitivity [161]	5
Figure 5. Linearity representation [161]	6
Figure 6. Hysteresis curve [161]	7
Figure 7. The architecture of MICS system	9
Figure 8. Modulation techniques used in biomedical sensors.....	12
Figure 9. The architecture of the wireless battery-less interface	13
Figure 10. The principle of ASK modulation [209]	13
Figure 11. PSK modulation waveforms. [162]	15
Figure 12. FSK modulation principle. [163]	17
Figure 13. Human's power resources.....	19
Figure 14. Energy harvesting methods used in the biomedical sensors	20
Figure 15. The efficiency of different powering methods for IMDs.....	20
Figure 16. Nuclear pacemaker [164]	22
Figure 17. Energy conversion scheme	22
Figure 18. The Basic work principle of piezoelectric IMD	23
Figure 19. Configurations of piezoelectric cantilevers [170]	24
Figure 20. Configuration of cymbal piezoelectric device [170]	24
Figure 21. A prototype of shoe mounted PEH [44]	25
Figure 22. Dependence of the efficiency of the linear branch cross-section dimensions [158]...27	27
Figure 23. The architecture of thermoelectric generator	28
Figure 24. Conceptual view of the electrostatic generator	29
Figure 25. Energy conversion principles of electret-free electrostatic IMDs. [208]	30
Figure 26. Electret-based electrostatics conversion model.....	31
Figure 27. Capacitor structure	31
Figure 28. Types of mechanical generators: a) relative movement, b) rigid body.....	33
Figure 29. Schematic of ultrasonic IMD. [165]	35
Figure 30. Infrared power radiation system [202].....	36
Figure 31. The architecture of Inductive coupling powering method	37
Figure 32. Types of topologies.....	39
Figure 33. The design of bio-fuel IMD	41
Figure 34. Types of body wireless communication	47
Figure 35. Overview of the future system	51

LIST OF TABLES

Table 1. <i>Table of comparisons between different wireless method.....</i>	8
Table 2. <i>Examples of comparisons of modulation techniques for IMDs.....</i>	18
Table 3. <i>Power consumption rates for different IMDs.....</i>	28
Table 4. <i>Comparison of Electromagnetic, Electrostatic and Piezoelectric powering methods....</i>	33
Table 5. <i>Comparisons between different electromagnetic power methods.....</i>	41
Table 6. <i>IEEE C95.1-1991 Maximum electric and magnetic field strength limits for public use</i>	45
Table 7. <i>Current trends addressing various threats to IMD security</i>	50
Table 8. <i>Comparisons between different power approaches</i>	50

LIST OF ABBREVIATIONS

ANSI	American National Standard Institute
ARQ	Automatic Repeat Request
ASK	Amplitude shift keying
BFC	Bio-Fuel Cells
BPSK	Binary Phase Shift Keying
DPSK	Differential Phase Shift Keying
FCC	Federal Communication Commission
FDA	Food and Drug Administration
EBC	Enzymatic Bio-Fuel Cells
ECG	Electrocardiogram
EMG	Electromyography
EOG	Electrooculography
ERG	Electroretinogram
FEC	Forward Error Correction
FSK	Frequency – Shift- Keying
IMD	Implantable Medical Device
IoT	Internet of Things
IMD	Implantable Medical Device
ISM	Industrial, Scientific and Medical
MFC	Microbial Fuel Cells
MICS	Medical Implant Communication System
NFC	Near Field Communication
PVs	Physiological signals
PSK	Phase Shift Keying
PTE	Power Transfer Efficiency
PEH	Piezoelectric Harvester
QoL	Quality of Life
RF	Radio Frequency
RFID	Radio Frequency Identification Technology
RX	Receiver
SAR	Specific Absorption Rate
SIR	Signal to Interference Ratio
TEG	Thermal energy generation
TX	Transmitter
WEP	Wired Equivalency Privacy
WMTS	Web Map Tile Service
WPA	Wi-Fi Protected Access
WPT	Wireless Power Transfer
WPAN	Wireless Personal Access Network

1. INTRODUCTION

Recently, the great variety of implantable medical devices (IMDs), have been designed for different medical purposes. These devices help to provide better treatment for patients for whom traditional and conservative treatment approaches have failed resulting in significant efforts being devoted to it. Bio-medical implantable devices were invented more than six decades ago. The first IMD was designed by E. Bakken; he developed the first cardiac pacemaker.

What is an implantable biomedical sensor? This is a device which is able to monitor and process information inside the human body; for instance, neurostimulators, implantable cardiac defibrillators, implantable drug delivery systems, pacemakers, insulin pumps and other devices.

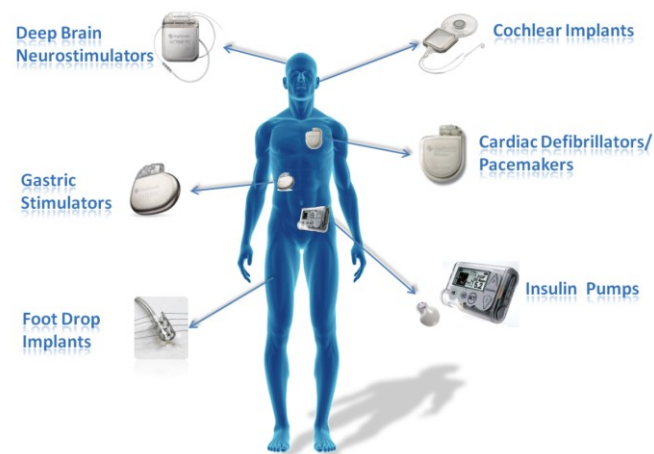


Figure 1. Examples of biomedical devices. [160]

The development of implanted sensors is significant, due to their use in diagnostics and monitoring health of patients. These sensors are able to continuously collect vital information from a person's body, such as force, temperature, and pressure inside the human body and provide it to their doctors or healthcare centres. Moreover, on-body monitoring can alert the patient of any health hazard and hence to promote rapid corrective clinical action if the patient is out of the clinic. Since the 1950s, when the first device was invented, a lot of research ideas and efforts were applied for designing completely new and reliable medical devices. These developments helped to improve quality of life and reduce expenses for treatment - especially for patients with chronic diseases and those who are located remotely from the clinic, or with limited access to doctors. Wireless connection provides benefits with respect to IMDs. It gives the opportunity to exchange data in both ways: uplink and downlink. Most of the time data is transferred from IMD to the server, which is located quite close to the person. Another benefit provided by wireless connection is the immediate updating of electronic health records. On the other hand, there are some concerns - for instance, cost, accuracy and security. On-body sensors, wearable devices and medical IoTs

matched with smartphones have also become popular in connection with a variety of sport and health applications.

In general, an implantable sensor is composed of two main parts, usually, the first part is attached to the skin or placed inside of the body, and the other part is a receiver, located outside of the body. The main purpose of the receiver part is to provide power to the IMD and deliver data to the doctor. Some of the IMDs are independent, meaning that these devices can regulate their operations depending on conditions. The main requirements for IMDs are based on power consumption, data rates, biocompatibility, dimensions and security. Battery lifetime is a very significant issue, in order to reduce chances for repeated surgery, it is vital to improving the lifetime of IMDs. Another critical requirement for IMD are the dimensions of the device; the continuous technological progress and the rapid development of semiconductors has led to rapid technological advances, with the dimensions of the devices getting smaller. However, the battery occupies a significant volume of the device, that's why it is vital to move towards battery-less IMDs. Wireless powering methods provide a wireless access to IMDs, such as RFID or NFC [125]. Human body resources are able to produce energy such as thermal, movements, vibration etc, which can be converted into electrical energy. Antennas are playing an important role in communications as well.

The thesis is organized as follows. Chapter 2 presents a short history overview of the implantable biomedical sensors which gives the main sensor's characteristics. Chapter 3 illustrates the main digital modulation techniques which are employed in biomedical sensors and literature reviews about recent publications. Chapter 4 focuses on the analysis of current harvesting methods for implantable medical devices and the review of real devices which are based on various powering methods. Chapter 5 is devoted to analysis of current challenges for implantable devices and powering methods and how to mitigate them. Chapter 6 summarizes the conclusions obtained by literature review and discusses future development perspectives.

1.1 Research Objective

The goal of the current thesis is to analyse and layout the advantages and drawbacks of wireless powering methods for implantable biomedical sensors and to define the current and future challenges of these approaches. This includes: analysis of the current situation on the market; which methods are being used currently; what kind of cutting-edge technologies are employed for implementing these approaches; and a review of modern publication about this topic.

1.2 Thesis Outline

This thesis will show: the analysis of existing power methods for implantable biomedical sensors; the main characteristics of the sensors; a brief introduction to the history of implantable sensors; a deep overview of modulation techniques which are being used currently for IMDs; research on the advantages and disadvantages of each modulation method; and a review of recent publications regarding these topics.

2. SENSOR TECHNOLOGIES

2.1 History of implantable biomedical sensors

Nobody can deny that our future is closely related to our past. Science and medicine develop hand in hand, with the medical device industry using cutting-edge technologies for the improvement of the quality of life for any human being. In this chapter the history of implantable biomedical devices will be explained.

People from all over the world suffer from different types of debilitating conditions such as blindness, deafness, diabetes, heart failure and others. Before the 1920s, diagnostics of these illnesses was a vital problem, which can reduce life expectancy or death. For instance, diabetes became a significant problem, due to the great variety of people that suffered from it. Insulin was one possible option for patients, but it demanded a lot of complex procedures. In the 1960s the first insulin pump was designed. It was a great breakthrough in medicine, but unfortunately, the dimensions of that design were enormous, and the mobility of the patients was therefore very low. Later, advances in technologies of insulin pumps reduced the sizes of devices. In 1980, the first insulin pump was developed with small dimensions; it can be compared to about the size of a calculator. The first implanted insulin pump was introduced later, and it was a revolution for medicine and diabetic patients. It brought a freedom to mobility and kept glucose level within acceptable ranges.

Nowadays, modern devices are controlled via various software algorithms and are able to track and adjust patients' glucose levels wirelessly. Another advantage of modern devices is an opportunity to check device status, the level of the battery, or possible malfunctions of the device. The control is achieved wirelessly via a Bluetooth interface into small tags that are placed on the patient's clothes.

The pacemaker device industry has followed the same path as the insulin pump; the first devices were bulky and unreliable, and that's why it didn't have a positive impact on the community. However, in 1930, Albert Hyman designed the artificial cardiac pacemaker. The dimensions of that device were quite small for that time, but nowadays such devices have much smaller sizes than 100 years ago. During the next 40 years, the pacemaker device has become smaller and smaller.

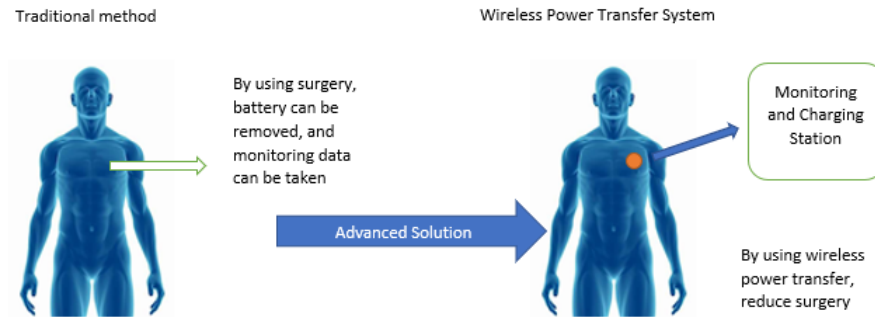


Figure 2. Cardiac stimulator before and after the wireless transfer

As a result, in 1960 the first successful implantation pacemaker was released, however, the first devices suffered from a limited battery life. Researchers employed nuclear batteries as a power harvester (plutonium), but due to the detrimental impact on health, they stopped using it. Later, in 1990, a new pacemaker was being released onto the market, employing a principle called “cardiac resynchronization therapy”.

The next step in pacemaker evolution was the ability to connect devices wirelessly. The first wireless pacemaker was introduced in 2009. The main advantages of the wirelessly powered device are the ability to control and to make a configuration remotely, and the freedom of movement for the patient. The use of wireless power transfer for pacemakers greatly reduced the risk of health problems and surgery risks. A great variety of research has been undertaken in order to optimize the transfer of wireless energy to pacemakers [136-138].

The evolution of pacemakers, insulin pumps, and mobile technology is presented in figure 3. According to the picture, we can see comparisons between each device. It illustrates one significant point, that the mobile devices industry is developing much faster the medical industry.

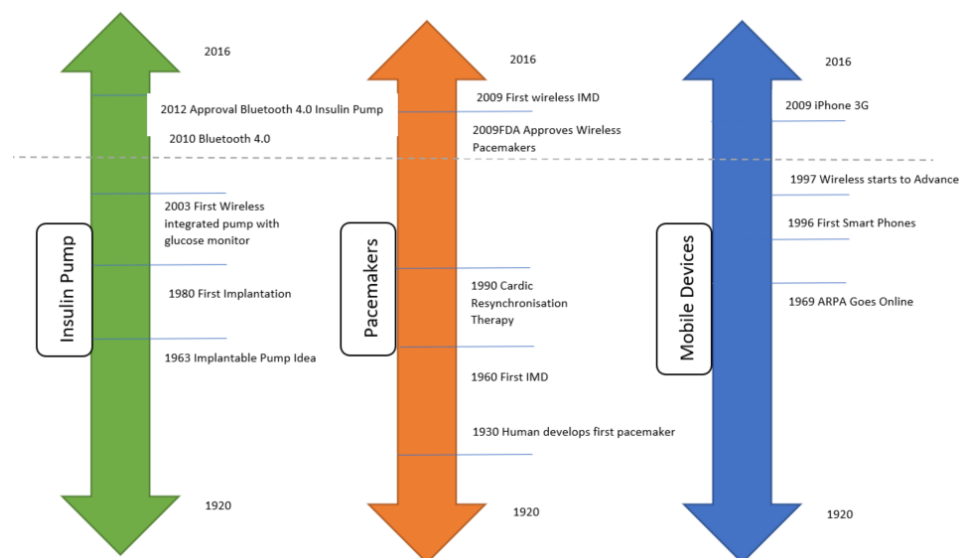


Figure 3. Timeline evolution of IMDs

2.2 Sensor characteristics

The main purpose of any sensor is to react to external influences and to give instructions to the system about these impacts. The simplest example of a sensor is a smartphone screen that reacts to the touch of your fingers. This screen is equipped with a temperature sensor, allowing you to react to the lightest and shortest touch of human fingers. Thus, sensors are able to convert an impulse into a measured signal. Sensors are the vital part of the IMDs and are based upon a very wide range of underlying physical principles of operation.

In this chapter the main definitions and characteristics of biomedical sensors will be presented, as well as the importance of the measuring process. Nobody can deny that biomedical sensors should be reliable, safe, and bio-compatible with a person's body. In order to understand the main characteristics of biomedical sensors, you need to understand the basic terminology which is used in sensor design.

2.2.1 Sensitivity

Sensitivity describes the ratio between the input and the output signals. It shows how much the output values change when the measured quantity changes. Some of the sensors measure very small signals, for instance, sensors which measure electrophysiological signals have very sensitive characteristics. Another example, some of the blood pressure transducers which have a sensitivity rating of 10 mV/V/mm Hg; that is, there will be a 10-mV output voltage for each volt of excitation potential and each mm of Hg of applied pressure. [161]

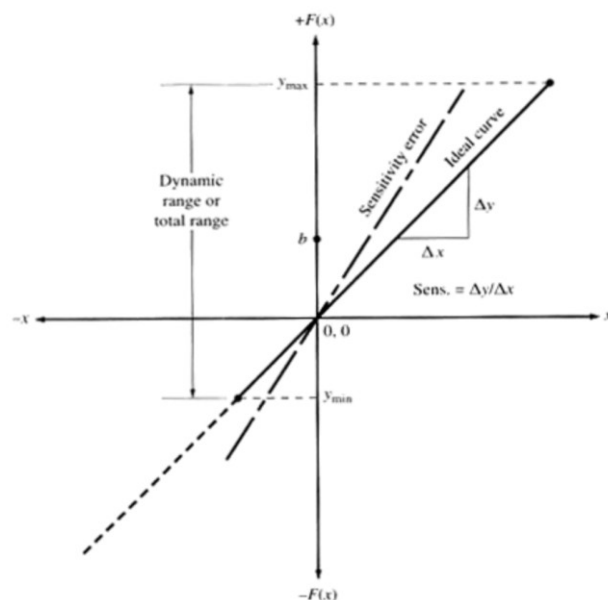


Figure 4. Sensors sensitivity [161]

2.2.2 Measurement range

First of all, it is better to understand what “range” means. Basically, the range of any sensor is the maximum and minimum values of an applied parameter that can be measured accurately. For instance, some of the blood pressure sensors have the minimum limit of -50 mm Hg and the maximum limit of +450 mmHg.

2.2.3 Precision

Precision refers to the “degree of a measurement’s repeatability in the same conditions”. If the measurement results remain the same after many experiments, it means that the sensor has a high precision.

2.2.4 Accuracy

Accuracy is “the expected error between the true values and actual values” measured by the sensor. Accuracy can be expressed as a percentage of the full scale.

2.2.5 Linearity

The linearity of the sensor is the maximum deviation between the actual values of the measurements and ideal results. Basically, linearity can be expressed in percent, according to the equation (1)

$$Linearity = \frac{\Delta L}{Y_{FS}} * 100\% \quad (1)$$

where ΔL is the maximum input deviation, Y_{FS} is the maximum full-scale input.

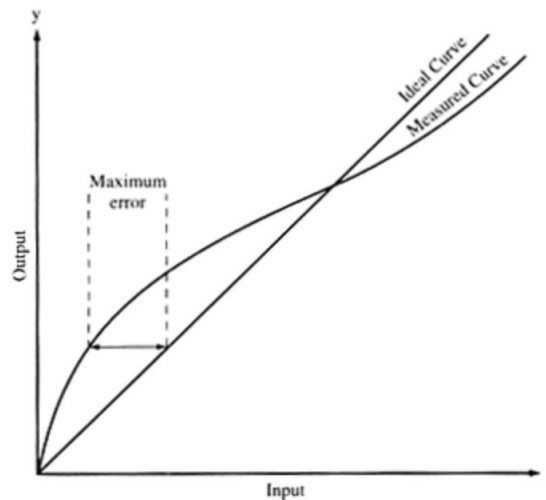


Figure 5. Linearity representation [161]

2.2.6 Hysteresis

The hysteresis of the sensor refers to some sensors, in which input and output characteristics have a non-linear trend, depending on input signal behaviour.

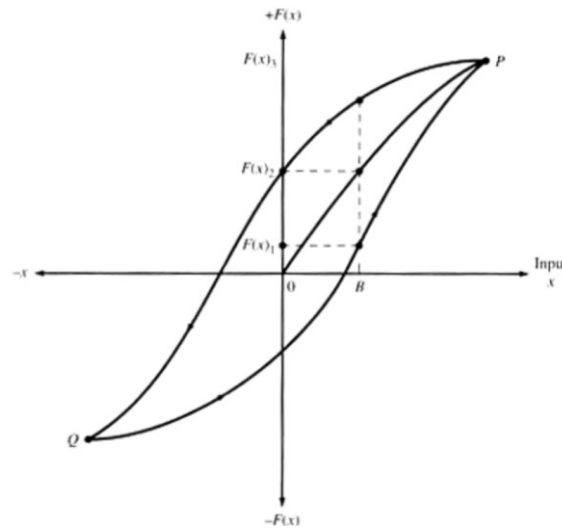


Figure 6. Hysteresis curve [161]

2.2.7 Resolution

The resolution of the sensor is the minimum detectable signal fluctuation. Resolution can be expressed as a proportion of the full-scale readings.

2.2.8 Response Time

The output value of the sensors doesn't change immediately when the input parameter change occurs. The response time shows the time needed for a sensor to react when the input signal is changed.

2.3 Frequency bands for wireless bio-medical implants

Currently, a great variety of wireless medical applications exist, such as implantable and telemetry devices. One of the crucial requirements for wireless implantable sensors is power consumption and small size. Most of the medical applications are used indoors and have quite a small range. Wireless IMDs utilize different frequency bands and share the radio spectrum with other devices. This leads to a lot of issues and concerns about performance, especially for applications which use license-free spectrum - which can cause interference, fading, multipath propagation, and blocking of the signals. A clear understanding of spectrum sharing (wireless coexistence and interoperability) is significant for the design of medical devices [139].

Wireless coexistence defines the ability of a wireless system to work in a shared environment, where other devices are using the same spectrum resources. There are three main factors which define the wireless coexistence: time, space, and frequency. Coexistence is possible if any one of

these requirements are met. First, sufficient distance between wireless networks. Second, the frequency separation between wireless networks [127]. Third, low overall occupancy of the wireless channel [2].

Table 1. Table of comparisons between different wireless method

Standard	Frequency	Range	Data Range
Inductive coupling	< 1 MHz	< 1m	Up to 30 kbps
Wireless Medical Telemetry System (WMTS)	608-614 MHz 1395-1400 MHz 1429-1432 MHz	35-70m	>250 kbps
Medical Body Area Networks (MBAN)	2483.5 MHz-2500 MHz	<1m	Up to 1 Mbps
802.11a Wi-Fi	5 GHz	120m	54 Mbps
802.11g Wi-Fi	2.4 MHz	140m	54 Mbps
802.11n Wi-Fi	2.4 MHz-5MHz	250m	48 Mbps
802.15.1 Bluetooth class 1	2.4 MHz	100m	3 Mbps
802.15.1 Bluetooth class 2	2.4 MHz	10m	3 Mbps
802.15.4 ZigBee	2.4 GHz	75m	40-250 kbps
Medical Device Radio Communication Service (MICS)	401-406 MHz	2-10m	250 kbps

Several frequency bands exist especially for medical devices, but many medical applications use unlicensed spectrum called the ‘ISM band’, in other words industrial, scientific, and medical band. Table 1 illustrates different wireless interfaces which are utilized by IMDs. These regulations and standards must be respected by all manufacturers. Each frequency band is designed for certain type of devices, for example, MBAN, WMTS, inductive coupling and MICS.

Inductive link is a reliable method for communication between an implantable device and a controller which is located out of the person’s body. However, this method has some drawbacks: the maximum separation between coils should not exceed 6 cm; the data rate is another issue - at approximately 30 kbps, the speed of data transmission is very low; and interference is a significant issue for inductive link medical applications, as the patient must be careful with these IMDs to ensure communication between sensor and receiver is always possible.

Medical Implant Communication Systems (MICS) transmit data from implants inside the human body to an external unit, in order to programme the IMD and control the patient’s data. An external device or controller can communicate with other systems, such as the internet, for the remote control of the patient’s conditions. The architecture of an MICS system is presented in Figure 7.

The implantable sensor is able to receive commands and can be reprogrammed from a doctor through a wireless connection. Patients can move freely with these sensors. Interference mitigation is the key issue for MICS systems because all data sent and received from IMDs should be accurate and reliable. There are different error correction methods such as FEC and ARQ.

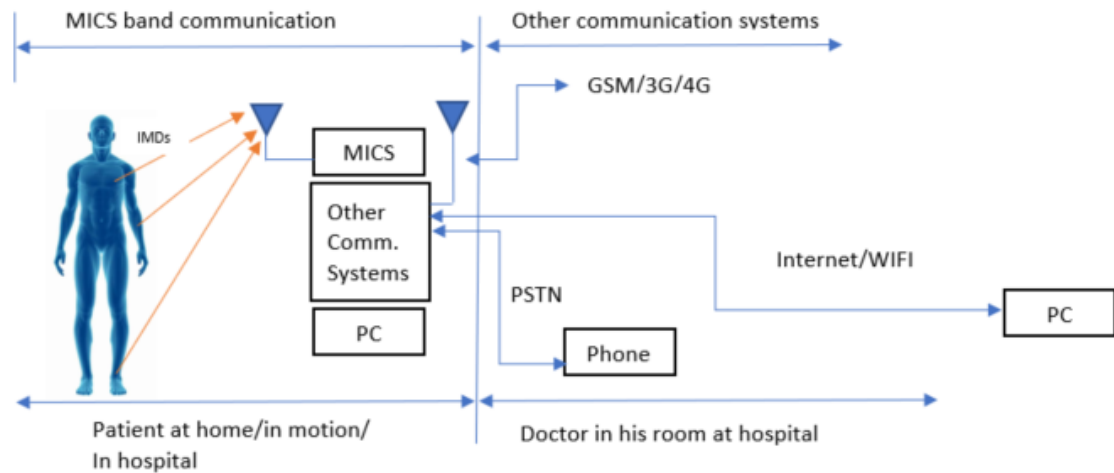


Figure 7. The architecture of MICS system

Wireless Medical Telemetry Systems are composed of sensors which measure important health parameters, and transmitters for delivering data through a radio interface to the receiver. This system utilizes different frequency bands from 600 to 1432 MHz all over the world. The UHF band (608 MHz to 614MHz) was originally reserved for radio astronomy. Therefore, users using this band should take into account that radio astronomy devices use the same band. The second frequency band (1395-1400 MHz and 1429-1432 MHz) was originally designed for government purposes such as military radar operations. Recently these bands have become available for WMTS. However, some countries have not followed these regulations, therefore frequency bands for WMTS need to be addressed and harmonised internationally. Without the acceptance of frequency regulations all over the world, the safety and quality of service provided by wireless medical devices are questionable. The WMTS is capable of two-way communication and providing high data transmission rates. There are certain limitations in this system: restricted bandwidth of only 14 MHz; video and audio transmissions are not possible; and each company which designs WMTS equipment uses their own protocols and interfaces, therefore devices from two different vendors are not able to communicate with each other.

Wi-Fi is the oldest wireless technology used in medical application, and has different sub-standards such as 802.11a, b, g, n, ac, ad. Each of these methods have certain sections of the ISM band. Wi-Fi allows transmission of both video and voice. Using the ISM band has advantages such as a wide bandwidth of 83 MHz in total, and devices can communicate with other devices. Wi-Fi networks can support a great variety of Wi-Fi compatible devices, such as access points, laptops, and monitors. Frequency management is not required, great propagation characteristics, low power consumption, easy to share spectrum resources with other devices. Wired Equivalent Privacy (WEP) - an algorithm for ensuring the security of Wi-Fi networks is used to ensure confidentiality

and the protection of transmitted data to prevent non-authorized wireless network users from listening. There are two types of WEP: WEP-40 and WEP-104, differing only in the length of the key. Currently, this technology is obsolete, as it can be hacked in just a few minutes. Nevertheless, it continues to be widely used. For security in Wi-Fi networks, it is recommended to use WPA. Wi-Fi Protected Access (WPA) is an improved version of the WEP protocol, therefore WPA has better performance than WEP, however, this method still has some vulnerabilities. In order to improve security characteristics, the next evolution of WPA has been released, called WPA2. This method has better security characteristics for wireless networks. On the other hand, certain limitations exist as well. The ISM band is unlicensed, and so other devices can cause interference. Encryption Wi-Fi is relatively poorly protected against hacking. Range and Wi-Fi transmission speed depend on the presence and intensity of the interference.

Wireless personal access network (WPAN) mainly uses two protocols: Bluetooth and ZigBee. Bluetooth is considered as a very short-range wireless technology, with low power consumption and small bandwidth. It is designed to replace cables and for communication between small devices or sensors which are associated with the human's body. Bluetooth utilizes the same ISM band as Wi-Fi and can also transmit video and voice.

2.4 Security of wireless medical devices

Security of IMDs and medical information will be the significant problem in the next few decades. Nowadays, most patients' medical records are paperless, and devices are used for collecting health data. Some of the devices are already available and very affordable, the main features being monitoring of heart rate, daily activities, and sleep cycles, in addition to the ability to illustrate it graphically.

Hospitals also widely use wireless technologies in diagnostics and treatment. The skyrocket development of wireless technologies has a beneficial impact on patients who are receiving these services. However, it is very important to keep this information secure and protect it from theft and hackers. For example, if someone is trying to steal information from medical records, it could be used for negative purposes or for the purposes of blackmail: therefore, it is important to store this data in a secure manner. Security includes a lot of factors, such as confidentiality, authentication, integrity, authorization, availability, and non-repudiation.

Recent studies have demonstrated the possibilities to attack IMDs. According to Halperin research paper [3], various implantable devices such as cardiac or pacemaker devices, have a lot of vulnerabilities to adversarial actions; this can result in information theft - such as personal information and medical history - or in the influencing of heart rhythms. This is possible due to an unprotected communication link between the IMD and the programmer. C. Li and A. Raghunathan also demonstrated possible security risks on real examples of the systems which are currently widely used, such as insulins pumps and glucose monitoring systems. The authors also offered possible solutions to protect systems against these attacks. They proved that the wireless link

between IMD and programmer should be controlled and secured to prevent illegal attacks from intruders. [4-5]

There are many researchers from all over the world addressing the security problems of IMDs. One of the common approaches is based on authenticating keys for establishing secure channel communication between IMD and programmer. However, this approach is not compatible with resource constrained IMDs. Hence, the IMD security should be based on tiny authentication schemes and symmetric encryption [6-8] or employ a resource-rich personal device (e.g. smartphone) to mediate communication between an IMD and an external programmer [9–11]. Another approach for the IMD security is associated with the accessibility issues of IMDs when an emergency situation occurs. Suppose an unconscious patient with IMD enters an emergency room (ER) of a non-primary-care hospital. In order for ER personnel to access the IMD the patient has, some backdoors should be integrated for the programmer. Even though several techniques [12–15] have been proposed, each of them have their own inherent security weaknesses.

3. MODULATION TECHNIQUES FOR IMDs

Digital modulation - the process of converting digital symbols into signals compatible with the characteristics of the communication channel. Each possible value of the transmitted symbols is assigned to some of the parameters of the analogue carrier wave. Manipulation - the way digital or pulse modulation, is when the carrier signal parameters change abruptly. When digital modulation is used most often, it is a discrete sequence of binary symbols - binary codes. Encoded primary analogue signal $e(t)$, which is a sequence of code symbols

$\{EN\} = EN(k) (n = 0, 1, 2, 3, \dots)$ - a serial number of the character - the number of code positions; m - code base, t. e. the number of its various components, which are converted into a sequence of elements (chips) signal $\{Un(t)\}$ of code symbols by exposure to high-frequency carrier wave $UH(t)$. As a rule, binary codes are used that $m = 2$. Usually, by modulating the frequency or phase of the carrier in the radio the pulses vary as determined by a digital code. Digital modulation provides much more information capacity and ensures compatibility with various digital data services. It also increases the security of information, improves quality and speeds up access to the communication system. On the other hand, the main drawbacks of the system with digital modulation are a significant expansion of the occupied frequency channels of bandwidth, and the need for accurate synchronization signals. Figure 8 illustrates the main types of digital modulation.

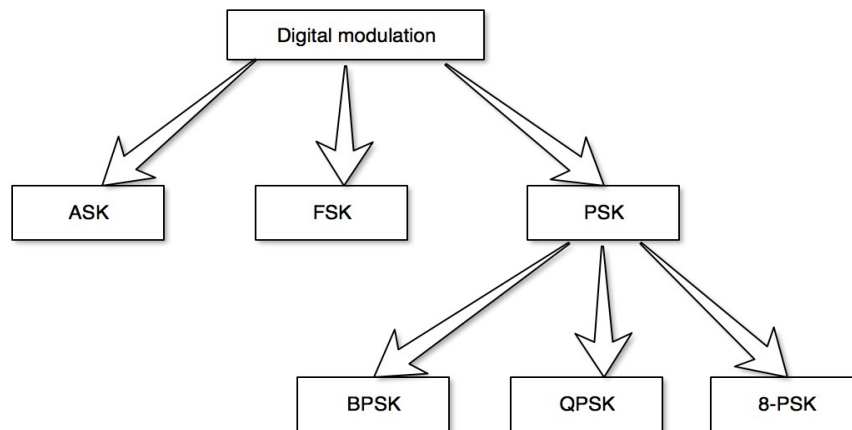


Figure 8. Modulation techniques used in biomedical sensors

The conventional wireless battery-less system link is used for 2-way communication between IMD and other devices. Figure 9 depicts the architecture of a wireless battery-less interface. Due to limitations in size and complexity of an implantable sensor, the signal processing part is located in the external unit. Power required for the implant modules - including a central processing unit (CPU), stimulators, and sensors - is transmitted by the external host via wireless interfacing. It

consists of two main parts: internal IMD and the external host system. The internal part is composed of a power harvester, a modulator for sending the signals from the sensor and its status for the external device, and a demodulator for receiving data from the sensor.

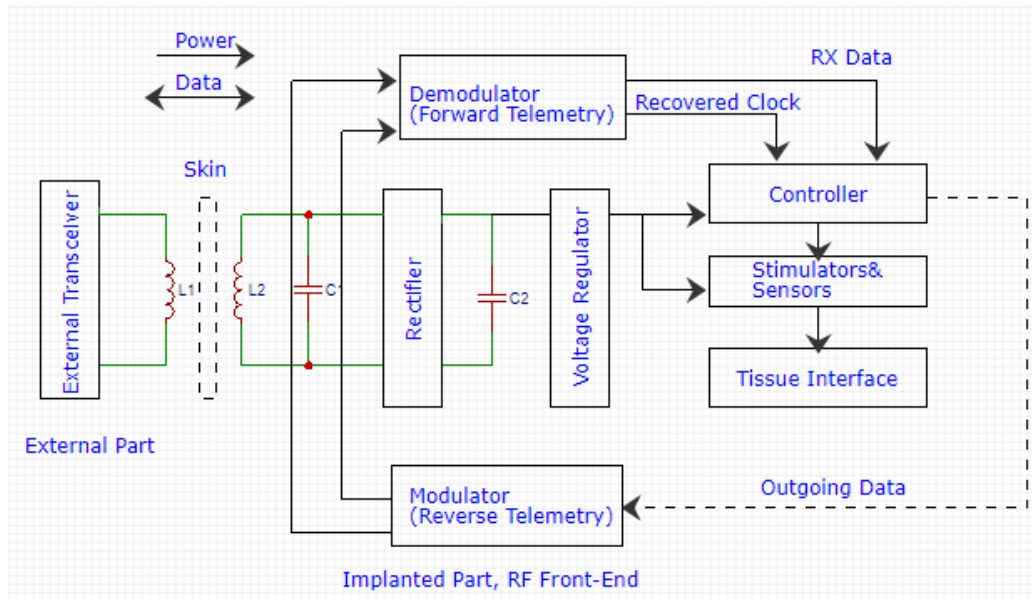


Figure 9. The architecture of the wireless battery-less interface

3.1 Principle of ASK modulation technique

Amplitude-Shift-Keying (ASK) modulation is one of the simplest digital modulation techniques which is used for implantable biosensors. However, this method has several limitations such as low data rates and high sensitivity for the amplitude noise. In ASK, the carrier amplitude is shifted between low and high values depending on the data at the input of the modulator [8]. There are two methods of ASK modulation which are perfectly suitable for the IMDs: coherent and non-coherent schemes. The non-coherent scheme has some advantages such as low power consumption, low complexity, and carrier phase detection is not used in this method. The coherent method utilises carrier phase information for detection. The principle of ASK modulation is illustrated in figure 10.

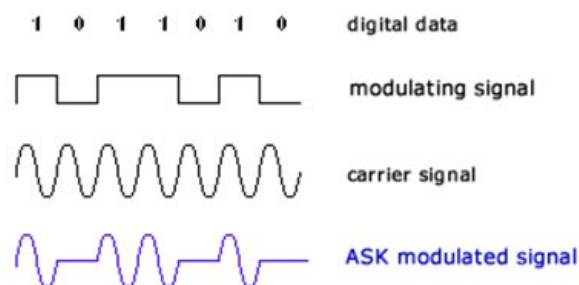


Figure 10. The principle of ASK modulation [209]

$$S_{ASK} = m(t) * c(t) \quad (1)$$

$$c(t) = A_c * \cos(2\pi * f_c * t) \quad (2)$$

Where $m(t)$ is the modulating signal (1 or 0), $c(t)$ the carrier signal, and f_c is the carrier frequency

It transmits 1s and 0s of data by transmitting with carrier or without a carrier. Bit 1 transmits with a carrier frequency, bit 0 transmits without a carrier.

The modulation index, h , is the ratio between the maximum and minimum voltage levels of the modulated signal.

$$h = \frac{\text{modulation amplitude}}{\text{carrier amplitude}} * 100\% \quad (4)$$

The modulation rate, r , is the ratio between data rate and operated carrier.

$$r = \frac{\text{data rate}}{\text{operated carrier}} * 100\% \quad (5)$$

3.1.1 ASK modulation method for implantable biomedical sensors

Reducing the chip area and power consumption are the key challenges for IMDs. In order to mitigate for this, developers reduced the number of passive elements in these devices. The C-less (no capacitor) ASK modulator for implantable neural interfacing chips has been developed by [16]. It is employed to transfer external data and regulate a stable output power.

In 2003, Najafi and Yu designed low-power interface circuits for IMDs based on ASK modulators. These circuits are composed of power-on-reset-block, power amplifier E class and low drop-out regulator. In this method, the ASK modulator provides a bit rate of 60 kb/s. However, this design has a very critical disadvantage with inaccurate synchronisation between clock and data signals [17]. Later, Djemouai demonstrated a new CMOS ASK demodulator for IMDs. This design is easy to implement, however, it has large dimensions. [18]. In order to solve that problem, Yu and Baitullah implemented a novel low power ASK demodulator without DLL [19]. This design is composed of low-power clock and data recovery IC. The main advantage of this method is accurate synchronisation and reduced power consumption.

In 2007, Lee developed a C- and R-less low-frequency ASK demodulator for IMDs. As a result, the number of elements was reduced to 12, with a total area of 0.003025mm^2 and power consumption at 1.01 mW [20-21]. A Low power consumption ASK modulator without passive elements was introduced by Zhi Lui. They improved the data rate up to 2 Mbps and reduced power consumption up to 84 μW , with a $0.3\mu\text{m}$ circuit size. A novel interface was represented by Li and Zhang consisting of a digital processing part and an analogue front end [23]. The system interface consists of the amplifier, low power circuit, ASK demodulator without passive components, and

a digital circuit. The power supply for this interface is 1.8V with power dissipation less than 2.75mW.

Another example of an ASK demodulator for implantable devices was implemented by G. Gudnason; this modulator has been tested with f_c in the range 1-15 MHz, with data rates up 100 kbit/s. Modulation indices for this case vary between 10-100% [24].

3.2 Principle of PSK modulation technique

Phase-Shift-Keying (PSK) is one of the most efficient digital modulations and is widely used in different communication systems. In this scheme, the digital data is encoded in the phase property of a carrier signal. Equation 6 presents corresponding s signals for this modulation.

$$S(t) = I(t) * \cos(\omega t) + Q(t) * \cos(\omega t + \frac{\pi}{2}) \quad (6)$$

$$A = \sqrt{\frac{2E_s}{T_s}}, E_s = 2 E_b, T_s = 2T_b \quad (7)$$

where E_s is the energy per symbol, T_s is the symbol duration.

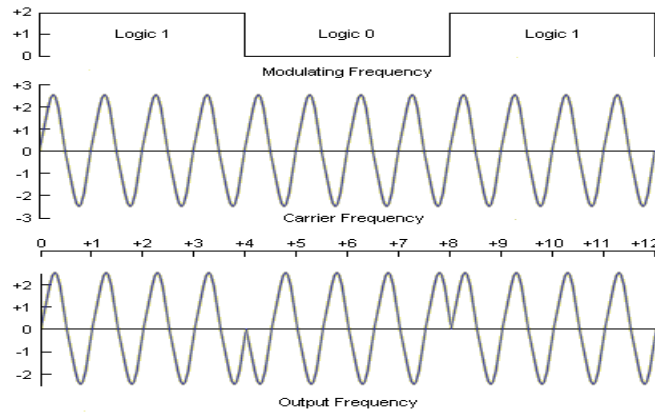


Figure 11. PSK modulation waveforms. [162]

In this system, a binary '0' is represented by a signal packet, the phase of which coincides with the phase of the previous packet sent, and a binary '1' is represented by a signal packet with a phase opposite to the phase of the previous packet. Such a scheme is called differential since the phase shift is performed relative to the previously transmitted bit, and not relative to some reference signal.

3.2.1 PSK modulation method for implantable biomedical sensors

Lower consumption and robust performance are the key advantages of PSK modulation. In 2004, Hu and Sawan presented a demodulator with the use of COSTAS loop [25]. The BPSK demodulator is composed of voltage-controlled oscillator (VCO), low-pass filter (LPF) and phase

shifters. The demodulator provides a high data rate of 1.12 Mbps with power consumption of 0.5 mW. The main feature of this design is a possibility to use BPSK and passive modulation, this method allows for full-duplex data communication. However, this design remains complex.

Due to this issue, in 2008 Lu and Sawan released a new version of their design with two modulators and demodulators based on OQPSK modulation [26]. This design has several advantages such as high data rates, and low complexity - which results in this system having low power consumption. Based on previous designs, Deng developed a version with modified COSTAS loop technology and improved data rate transmission up to 8 Mbps, on 13.56 MHz carrier frequency and 0.75mW power output [27].

Inductive coupling links are a very popular solution for transfer of power to the IMD, however, this design is complex. In 2006, Zhou designed a new system which provides a high data rate DPSK telemetry developed to mitigate interference without using a high-order filter [28]. This system operates at 1MHz carrier frequency for power transmission and at 20MHz carrier frequency for data transfer. This system has some disadvantages such as high-power consumption and big size.

Later in 2008, Zhou developed a previous design using DPSK modulation to reduce the interference for a dual-band configuration [29]. The data telemetry and power signals interfere with each other and as a result, they produce interference. In order to solve this problem PLL less scheme should be used. The demodulator provides up to 2Mb/s data rate, and this system operates at 20MHz. For reducing interference at the receiver, DPSK modulation is used for IMDs through dual-band telemetry [30]. The DPSK modulator provides up to 4 Mbps and operates at 22 MHz.

Some of the complex implants, such as retinal implants, require reliable and high-speed data transmission. Elamary designed a BPSK modulator which provides high data rates up to 20 Mbps and operates at 20 MHz frequency. The main feature of this design is an incredible data to carrier frequency ratio of 100% and low power consumption. The BPSK modulator is implemented based on the non-coherent method [31,32].

3.3 Principle of FSK modulation technique

Frequency – Shift- Keying (FSK) is another digital modulation method, which is widely used in wireless transmission for biomedical applications. Figure 12 shows two oscillators forming $s_0(t)$ and $s_1(t)$ oscillations at different frequencies. There is also an electronic key controlled by a digital signal $b(t)$ so that when a logical "1" is transmitted, a signal $s_1(t)$, is sent to the output and when a logical "0" signal is transmitted, a signal $s_0(t)$ is sent. Thus, the frequency of the output signal is "manipulated" depending on the bit sequence. BFSK modulation method can be described by equations 8 and 9:

$$S_1(t) = A * \cos(2\pi * f_1 * t) \quad (8)$$

$$S_2(t) = A * \cos(2\pi * f_2 * t) \quad (9)$$

The main advantages of FSK are lower susceptibility to errors than ASK, simplicity in the implementation, increase in the immunity of radio reception, power of the transmitter is better used (since the power of the signal remains unchanged during the whole process of modulation), and passband centralized between f_0 and f_1 with low Q to pass enough power for both frequencies. On the other hand, there are some disadvantages: requires complex demodulator, large bandwidth, and the synchronization between transmitter and receiver is complex.

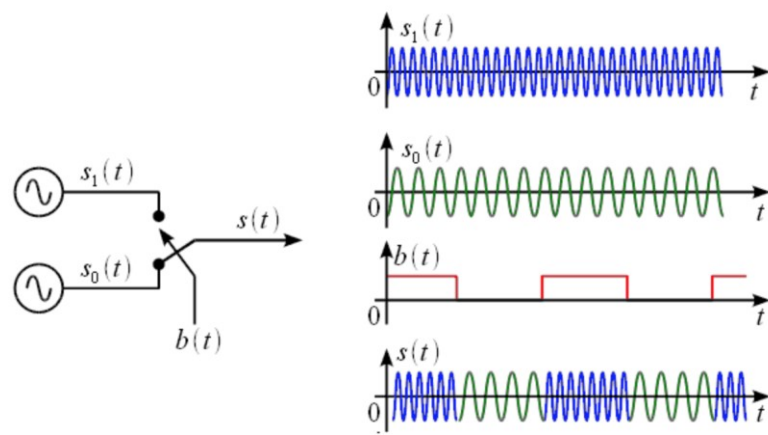


Figure 12. FSK modulation principle. [163]

3.3.1 FSK modulation method for implantable biomedical sensors

FSK modulation is widely used in wireless transmission for wearable and implantable biomedical sensors. It provides high data rates and low power consumption. In order to get low power consumption, FSK transmitters should be adjustable in case of data rate, because different sensors need to have various data rates, for example, transmitting physiological information requires a transmitted data rate of about several kbps. However, for transmitting physiological image information, a data rate of several megabits per second is required. Horng-Yuan Shih has implemented this type of ultra-low FSK transmitter with power consumption ranges between 378 μ W to 424 μ W and data-rates varying from 200 kbps to 2 Mbps [33]. Zhinheng designed 2 and 4 FSK demodulators. This novel demodulator improves the bit error rate (BER) performance and improves decision accuracy by generating additional zero-crossings - however, it has a very high-power consumption at about 3mW from a 3V power supply.

In 2004 Ghovanloo and Najafi developed an FSK modulator based on the inductively coupled link model [34]. This modulator consumes 0.38mW of power at 5V. Later, in 2006 Ahmet Tekin

designed a low power FSK modulator for transceivers in the MICS band. This modulator provides up to 20 kbps data rate. [35] The size of the design is $0.18\mu\text{m}$ with CMOS process and a very low power consumption of $33.41\mu\text{A}$ at 1.5 V supply. Low power consumption and simple and reliable architecture are significant factors for non-invasive implantable biomedical sensors. This modulator developed by Zhu [36] has a relatively simple design; this circuit integrates the modulation functionality into the oscillator itself by using the data signal to control the oscillation frequency and producing carriers for different types of monitoring signals [35]. Supporting data rates are from 450 kbps up to several Mbps, with low power consumption of $1\mu\text{A}$ at 2.5V.

Table 2. Examples of comparisons of modulation techniques for IMDs.

Modulation technique	ASK	FSK	BPSK/DBPSK
Carrier frequency	1-250 MHz	2-433 MHz	10-20 MHz
Data rates	0.004-1 Mbps	0.18-1.5	0.18-0.5
Coherent or non-coherent	Non-coherent	Can be both	BPSK is coherent, while DBPSK can be non-coherent
Power consumption	$0.062\text{--}70\mu\text{W}$	$33.41\mu\text{W}\text{--}3\text{ mW}$	$31.5\mu\text{W}\text{--}6.2\text{mW}$
Noise performance	Poor performance, as it is heavily affected by noise and interference	Better noise performance than amplitude modulation schemes	BPSK generally shows better error performance than ASK and FSK, but the error probabilities are double with DBPSK
Cost efficiency	Low cost	Simple, low cost implementation possible	Usually implementation is complex and more costly than other techniques
Applications	Neural system Physiological signal Cochlear implant Telemetry Applications Endoscope	ECG General Biological signal Physiological sensors	Brain stimulator Cardiac stimulator Neuromuscular stimulator General

4. POWERING METHODS FOR IMPLANTABLE BIOMEDICAL SENSORS

Implantable biomedical sensors can be divided into two categories. The first category includes sensors powered by sources surrounding the implants. Human daily activities such as motion, breathing, sleeping, and body heat are great sources of thermal and kinetic energy. For instance, everyday walking can produce 1500 mW.

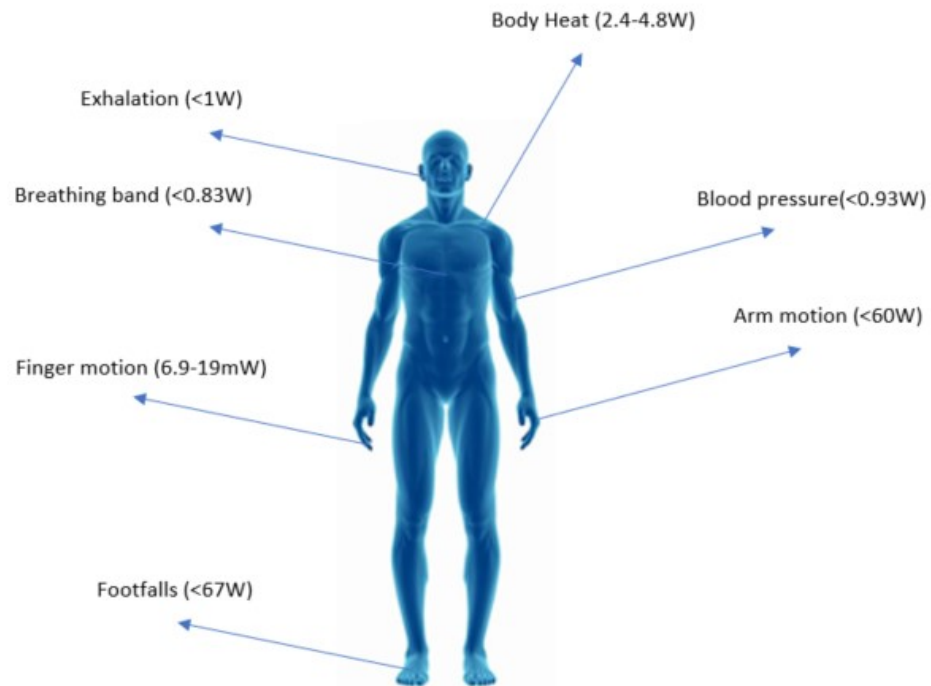


Figure 13. Human's power resources

This property can produce enough energy to generate a few hundred milliwatts. Kinetic energy is an easily accessible source for IMDs. There are a great variety of possibilities for converting kinetic energy into electrical energy. For example, piezoelectric materials, electrostatic, or electromagnetic mechanisms are possible solutions for this purpose. The brief resumé of a human's potential power resources and various body actions are provided in figure 13.

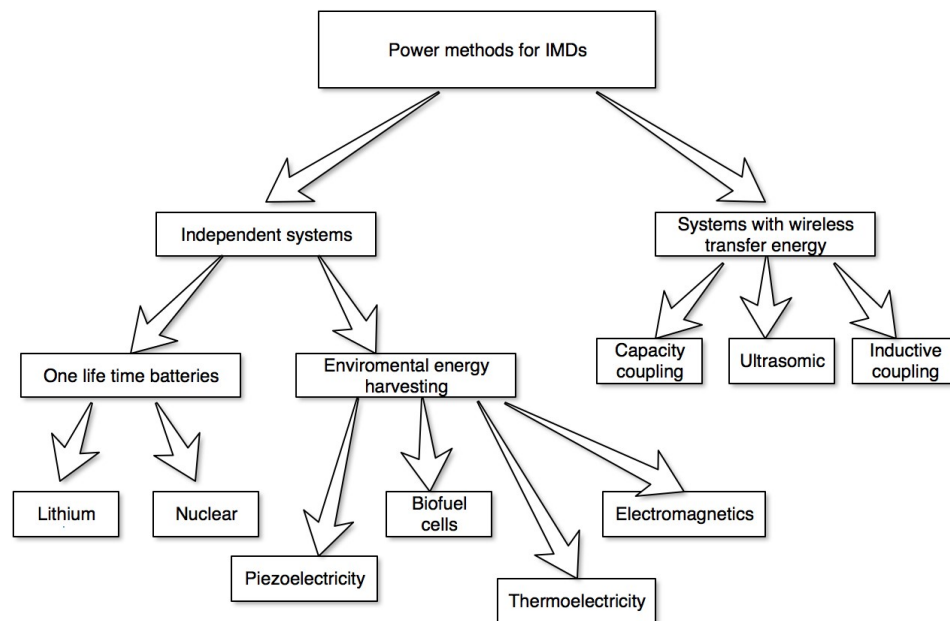


Figure 14. Energy harvesting methods used in the biomedical sensors

Instead of using body resources, another feasible solution is to supply energy to the implantable sensor through an external unit. In this case IMDs can use ultrasonic, optical or electromagnetic harvesting systems. Optical power delivering systems consist of a photovoltaic cell placed inside of the IMD which receives power from a laser operating in the NF or IR range. Inductive power transmission is one of the most reliable and efficient ways of delivering power to IMDs with small sizes. The basic principle of this system consists of two antennas, one antenna is for TX and another for RX, these antennas are used for power transfer. The ultrasonic method is one of the more modern ways to transfer energy, due to the immunity from electromagnetic modulation and high efficiency. Figure 15 depicts the efficiency of different powering methods for IMDs.

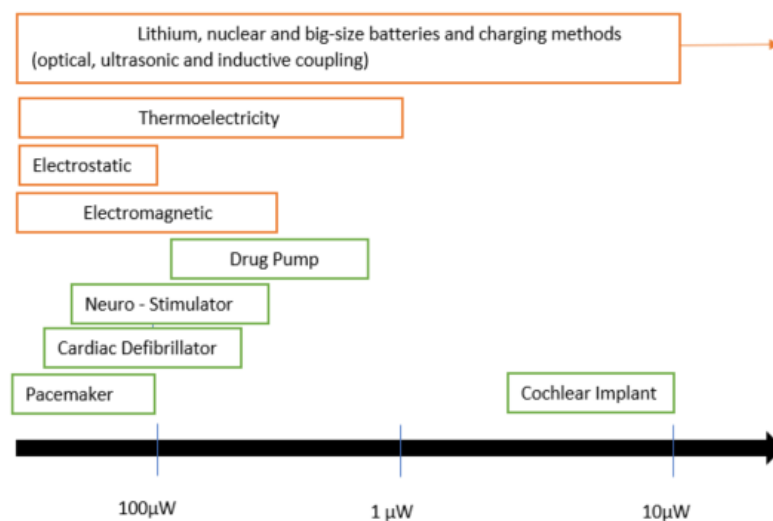


Figure 15. The efficiency of different powering methods for IMDs

4.1 Lithium batteries

The main purpose of the battery is to supply electrical energy to a portable device. There are two types of batteries which are used in IMDs: primary and secondary batteries. Primary batteries provide high output power and current and are used in pacemakers. Secondary batteries provide relatively small output power and current, therefore these batteries are used in less power demanding applications.

Some examples of primary batteries are: lithium-iodine, lithium-manganese dioxide, and lithium-carbon monofluoride batteries. Greatbatch invented lithium-iodine batteries in 1973. Lithium-iodine batteries have perfect parameters such as extended battery life and high voltage output, which make them suitable for powering small electric devices.

These accumulators are used in pacemakers, cardiac defibrillators, and cochlear implants as a reliable energy source. Li-ion batteries provide voltage up to 4V, showing better performance than other types of batteries. These batteries have a very high-power density around 200 W·h/kg. Lithium-manganese dioxide batteries have been developed for devices with additional features which require power in the mW range. Lithium-manganese dioxide batteries were invented by Ikeda in the 1970s; these batteries have outstanding characteristics including high energy density and good storage and discharge characteristics. The main applications which employ these batteries are pacemakers, neurostimulators, and drug delivery systems. The lithium-manganese dioxide batteries are composed of a lithium anode which is placed in the centre of the cell and surrounded by two cathodes. The battery has a high level of stability and low self-discharge rate. The volume of these is 10.5 cm³ and it has energy density of 0.588 Wh/cm³, with a capacity of 2.5 Ah [210].

Lithium-ion batteries can be considered as secondary batteries. These batteries can be distinguished by the type of cathode material used. The carrier of the charge in the lithium-ion battery is the positively charged lithium ion, which forms a chemical bond with either graphite, oxides, or metal salts, for instance, to form LiC₆, oxides (LiMnO₂) and salt (LiMnRON) metals.

As a conclusion, the primary systems employ lithium metal anodes and various cathode systems. These batteries provide suitable power levels for different IMDs with different energy consumption rates. Secondary batteries were developed for specific implantable devices which have an option to be charged while remaining implanted.

4.2 Nuclear batteries

Nuclear batteries are another type of powering method for IMDs. The basic principle of nuclear batteries is converting energy carried by particles emitted from radioisotopes into electrical energy. Usually, nuclear batteries utilize plutonium, because it has a half-life of 88 years and output power reduced by 10% in 10 years. Nuclear batteries were introduced in the medical industry in 1973.



Figure 16. Nuclear pacemaker [164]

The main advantages of these batteries are that they have a very long life, with stable output characteristics. For instance, the Betacel produced by Medtronic, Inc can provide $50 \mu\text{W}$ of power with small dimensions. [38] On the other hand, there are some disadvantages such as the extreme toxicity of plutonium. [39-40]; only $1 \mu\text{g}$ can have a fatal effect.

Nuclear batteries are mainly used in pacemakers with each pacemaker having special shielding to prevent additional radiation contamination. As a result, plutonium powered pacemakers produce radiation at approximately 100 mrem per year. Normally a person gets an average 360 mrem per year from different sources such as solar radiation and medical sources. Consequently, plutonium-based pacemakers have been recommended even for a pregnant woman.

Nuclear-powered pacemakers stopped being produced in 1980, due to the introduction of lithium batteries.

4.3 Piezoelectricity power generators

The piezoelectric effect was revealed by the brothers Curie in 1880 [40]. The Curies proved that special structures are able to provide a proportional electrical polarization with respect to applied mechanical stress [211]. Energy conversion through piezoelectricity is illustrated in figure 17.

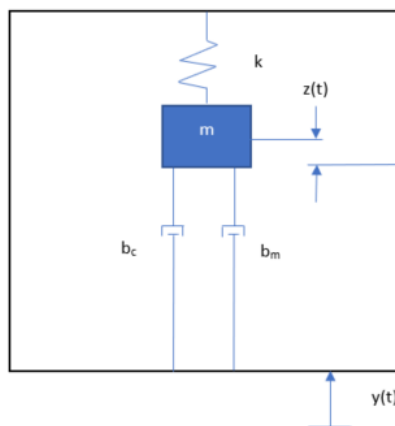


Figure 17. Energy conversion scheme

$$m\ddot{z} + (b_e + b_m) * \dot{z} + kz = -m\ddot{y} \quad (10)$$

Where y is the base displacement, k the spring constant, z is the output tip displacement, m the lumped mass, b_m and b_e are the mechanical damping and electrical damping coefficients respectively. The power output of the system, P , is calculated using:

$$P = \frac{m\xi_e A^2}{4w(\xi_e + \xi_m)} \quad (11)$$

Where w operation frequency, A is the acceleration input of the input vibration,

There are two types of piezoelectric effect: ‘direct’ and ‘opposite’. The ‘direct effect’ is used to transform mechanical energy into electrical energy and the ‘opposite effect’ has the same principle, but vice-versa. Piezoelectric materials have three operational modes: transverse mode refers to when the force applied along a Y-axis generates charges along the X-axis; the Longitudinal effect and the Shear effect produce charges proportional to the applied forces.

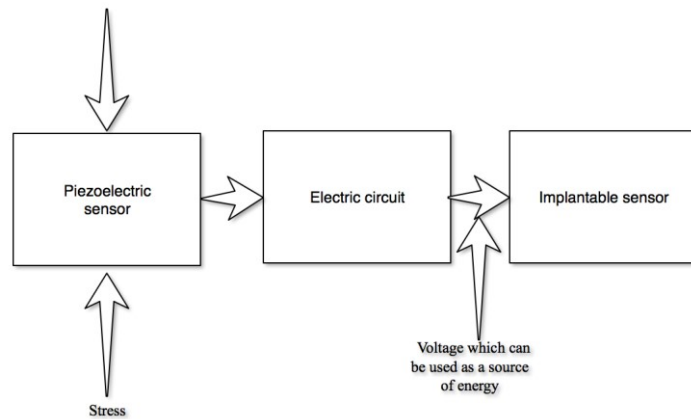


Figure 18. The Basic work principle of piezoelectric IMD

Piezoelectric sensors convert mechanical energy - for example, body motion - into electrical energy. Physical and chemical processes inside of the human body can be employed in order to provide a power source for various wearable devices and IMDs. There are two types of body motion: continuous and discontinuous. Continuous motions such as breathing and heart beating can generate up to 2W. Another type of motion is discontinuous, for instance, walking, jogging, and cycling.

There are four different materials which can be used for piezoelectric devices: ceramics (lead-zirconate-titanate (PZT)), polymers, single crystals, and composites. Composites, crystals and ceramics have better characteristics than polymers. However, polymers are more suitable for use cases where the IMD will be subjected to a large amount of bending. Most of the piezoelectric devices are built on ceramic elements - especially PZT - due to cheap prices and outstanding characteristics. The efficiency of piezoelectric material depends on resonant frequency; in order

to get maximum power output, piezoelectric devices should precisely tune to the resonant frequency. The piezoelectricity coefficient depends on materials.

There are two main conventional configurations of piezoelectric devices: cantilever beams and disks. Disks are divided into two categories: cymbals and diaphragms. The cantilever shape is one of the most common configurations for converting vibrations into electrical energy, due to its simple design and low resonant frequency. Figure 19 depicts two types of cantilever shape, A figure shows unimorph and B figure show bimorph design.

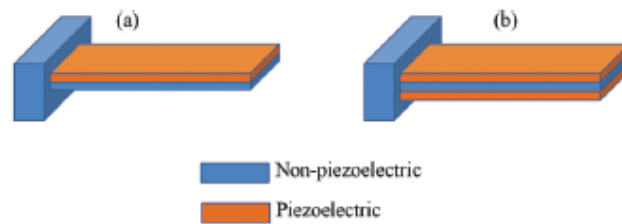


Figure 19. Configurations of piezoelectric cantilevers [170]

The unimorph design is composed of thin piezoelectric and non-piezoelectric layers. In such a configuration, there is only one active layer (piezoelectric) and the other layer is just a steel plate. Another configuration is bimorph, composed of two piezoelectric layers, hence both are active. This configuration is used for improved power output of the design. In piezoelectric layers poled directions are usually orthogonal to the planar directions. After literature review about this topic, a great number of energy harvesters are designed with the use of bimorph or unimorph configuration. However, the bimorph structure appears more beneficial and widely used, due to better output power characteristics for the same volume of device compared with the unimorph design.

Cymbal piezoelectric converters are another type composed of a steel end-cap and a piezoelectric disk. The working principle is as follows: when the axial stress is applied to the steel surface of the device, this causes deformation which converts and amplifies the axial stress into radial stress in the piezoelectric disc. The energy efficiency of this system is higher than for the cantilever beam-based systems. As an example, cymbal piezoelectric devices can produce up to 52 mW under 70N force, with dimensions of 29 mm in diameter with 1mm thickness [207]. However, this design is not suitable for applications with high magnitude vibration sources.

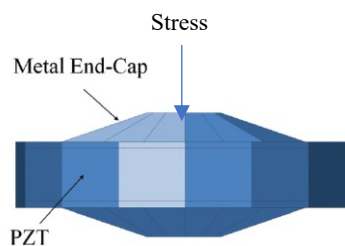


Figure 20. Configuration of cymbal piezoelectric device [170]

The circular piezoelectric diaphragm is another type of design. It operates in the same way as piezoelectric cantilevers. To construct a piezoelectric circular diaphragm transducer, a thin circular piezoelectric ceramic disc is first bonded to a metal shim and then the whole structure is clamped on the edge, while piezoelectric cantilevers are only clamped at one end of the cantilever beam [170].

A great variety of researchers have investigated how to use discontinuous motions as a source of energy [41-43]. Obviously, continuous motions such as breathing provide less power compared with discontinuous motions. For instance, heartbeat vibrations are a rich energy source, meaning it is possible to convert vibrations into energy supply for pacemakers with the use of linear and non-linear PEH [182,183]. Researchers from the MIT Lab designed a device which generates electrical energy from kinetic energy (human walking). This device converted mechanical energy into electrical energy for wearable applications. At the same time, Starner [174] proposed his idea about the implementation of piezoelectric elements which can be integrated inside shoes and rotary generators that are able to collect and store energy from running shoes. In 2001, Paradiso designed integrated piezoelectric elements called polyvinylidene fluoride. These piezo elements are placed in shoes and generate electricity from bending of the foot [44]. One element is located in the heel and another in the toe region; the design provides up to 8.3 mW. However, this design is suitable only for persons who are able to move freely. Another energy efficiency design was proposed by Rome [175]; he designed a spring-loaded rucksack to gather electrical energy from walking. However, that design was based on an electromagnetic system. Grandstrom decided to replace that system with piezoelectric straps [176]. Zhu developed a piezoelectric generator to convert the movement of a knee joint into electrical energy [179]. Renaud proposed a piezoelectric harvester to collect energy from human limbs [177]. A head-mounted piezoelectric harvester was developed by Voix and Delnavaz, which is able to collect energy from jaw movements. Later, Ertuk developed an advanced broadband harvesting system based on a piezomagnetoelastic structure, which is more efficient than other existing systems [178]. This is a short review of designs based on PEH, which are able to generate energy from the human walk. Moreover, different PEHs have been developed in order to collect energy from multi-directional vibrations [180-181] but are not applicable to walking harvesting, due to the nature of the movements. However, in 2017 Fan and Lui [172]

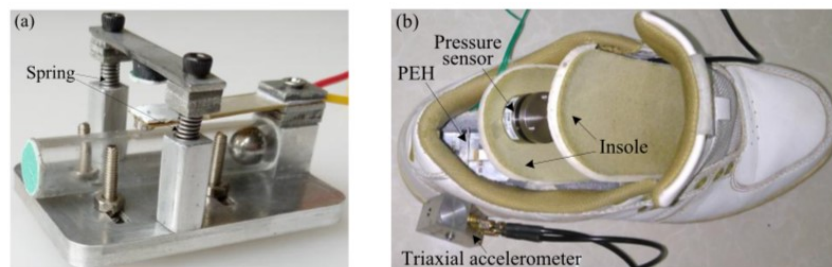


Figure 21. A prototype of shoe mounted PEH [44]

developed a shoe mounted non-linear PEH which was able to convert energy from various motions produced by the foot. The design is composed of a piezoelectric cantilever beam, a crossbeam, and

a ferromagnetic ball [172]. The output power of PEH is up to 0.35 mW, however, it works only in certain scenarios - specifically when the walking velocity is within a certain range. Nevertheless, this PEH is able to produce a large amount of power compared with other PEHs, but on the other hand the output of most current PEHs provide slightly lower output power in comparison with electromagnetic harvesters; For example, some electromagnetic harvesters produce up to 0.5W in similar scenarios.

As a conclusion, piezoelectric power generators are quite efficient, but on the other hand, they need a lot of movement to generate sufficient power.

4.4 Thermoelectricity

Presently, chemical power suppliers are a very popular solution for low-powered devices. Despite continuous quality improvements of chemical power sources, they still have some limitations such as short battery life, large geometrical dimensions, and negative environmental impact. Consequently, researchers from all over the world are looking for better power sources. Thermoelectric generators are one of the possible approaches, because they have long battery life and a high level of reliability. Thermoelectric harvester technologies are based on the Seebeck effect. The German physicist Thomas Johann Seebeck discovered that a temperature difference between two different electrical semiconductors produces a voltage difference between the two substances. When heat is applied to one of the conductors, heated electrons move towards the cooler ones. The voltage output produced by the Seebeck effect is only a few microvolts.

On the other hand, the Seebeck effect generates low voltage output - typically a few microvolts - only if the temperature difference is big enough. The efficiency of these generators is possible to calculate using the Carnot principle:

$$\eta = 1 - \frac{T_c}{T_h} = \frac{T_h - T_c}{T_h} \quad (12)$$

Where η is the Carnot efficiency, T_h and T_c are the hot and cold temperatures in Kelvin. The efficiency of thermoelectric generators is dependent on the resistance coupling. The physical model of a thermoelectric generator is illustrated in figure 23. The temperature differences between different parts of the body form a temperature gradient. This gradient can be applied to the thermoelectric module, which produces sufficient electric power. There are two modes of thermoelectric generator (TEG): maximum power (or matched load) mode, and mismatched load.

Let us consider one case in which the required output power must be 1.5 V, thus thermoelectric power force should be equal to 3V. According to experiment measurements, if the thermal gradient between the temperature of a person's body and the ambient temperature equals 5° C the Seebeck coefficient equals 200 mkW/K, the thermoelectric power force 3 V, and the number of branches in TEG equal 3000.

In matched load mode, the resistance of TEG, r , is equal to load resistance, R , at the maximum current value, I_{\max} . Let's assume that maximum efficiency of TEG could be reached with the following values: $I_{\max} = 36 \text{ mA}$ and $R = 41,7 \text{ k}\Omega$, the number of branches, $N = 3000$, where the height of each branch equal 5mm with cross-sectional dimensions $0.06 \times 0.06 \text{ mm}$ and the spacing between each branch is 0.02 mm. Thus, the total geometric dimension of TEG is $4.4 \times 4.4 \times 5 \text{ mm}$. However, cross-sectional dimensions as described above have some drawbacks such as complex technological implementation. On the other hand, increasing cross-sectional dimensions causes mismatched loads between power supplier and load, and can also decrease the efficiency of TEG. Therefore, it is very important to define the best branch dimensions which can provide high efficiency of the TEG. For these purposes, we can use the mismatched load mode.

Mismatched load mode

The maximum efficiency defined using the next equation (13)

$$\eta = \frac{1}{4} \frac{T_1 - T_2}{T_1} Z \frac{T_1 - T_2}{2} \quad (13)$$

Where T_1 and T_2 are the temperatures on different sides of TEG, Z quality factor of material.

According to calculations, if the temperature difference is 5°C , the maximum efficiency that can be reached is 0.4%. Let's investigate the dependency between efficiency and cross-sectional dimensions of the branches. In this case, efficiency calculates as equation 14

$$\eta = \frac{W}{Q_h} \quad (14)$$

$$Q_h = k \frac{S_m}{l} \Delta T N \quad (15)$$

Where Q_h is thermal power, which perceives TEG, k is the coefficient of thermal conductivity, and S_m is the cross-section square of the branch. From those equations we can observe that increasing cross-section dimension of the branches causes a boost in thermal power and it decreases the efficiency of the TEG.

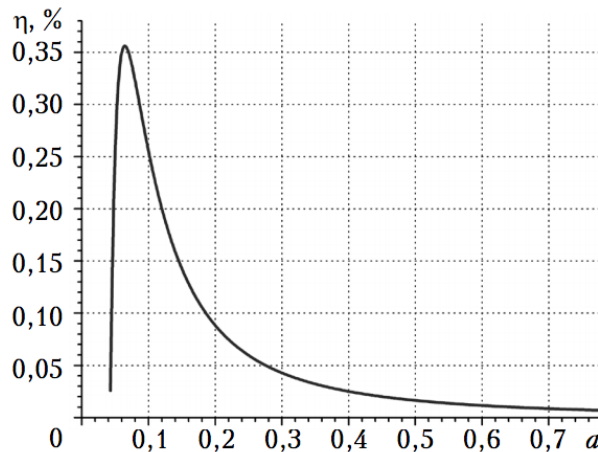


Figure 22. Dependence of the efficiency of the linear branch cross-section dimensions [158]

From figure 22 we can see that increasing linear cross-section dimensions from 0.06 to 0.5mm, the efficiency of the TEG reduces by 5-10 times. However, we can improve efficiency by decreasing cross-section dimensions of TEG. Thermoelectric generators are usually made from bismuth telluride or polycrystalline silicon-germanium film.

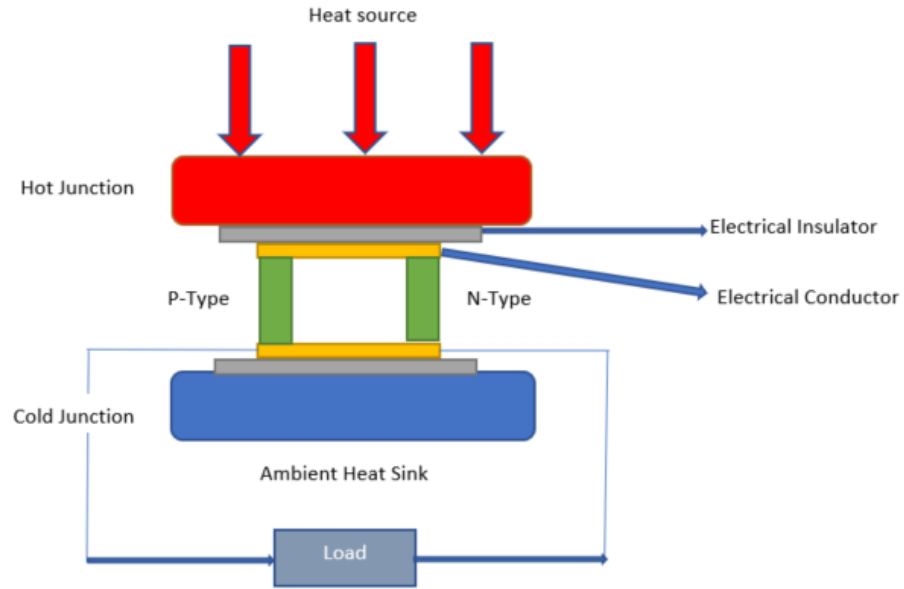


Figure 23. The architecture of thermoelectric generator

The thermoelectric module consists of two types semiconductors, p and n. The voltage generated by this module can be calculated according to the following equation:

$$V = \int_{T_h}^{T_c} (S_B(T) - S_A(T)) dT \quad (16)$$

Where S_B and S_A are the Seebeck coefficients of the two materials.

There are a great variety of existing systems which are implemented based on thermal energy conversion. João Paulo Carmo [158] presented one possible solution for powering low-power electronics. Table 3 illustrates power consumption rates for different IMDs.

Table 3. Power consumption rates for different IMDs

Implanted Device	Power Requirements
Cardiac Pacemaker	30-100 μ W
Cardiac Defibrillator	30-100 μ W
Drug Pump	100 μ W-2mW
Cochlear Implant	Up to 10mW

As a conclusion, we can observe that thermoelectric generators are only suitable for low power IMDs, because thermoelectric generators are able to produce only a few microwatts. In order to increase power output, thermoelements should be connected in a cascade. However, this can cause problems such as the big size of the system, and low reliability.

4.5 Electrostatic generators

The working principle of electrostatic generators is based on electrostatic induction. These generators convert mechanical energy into electrical energy by moving part of the transducer versus an electrical field [212].

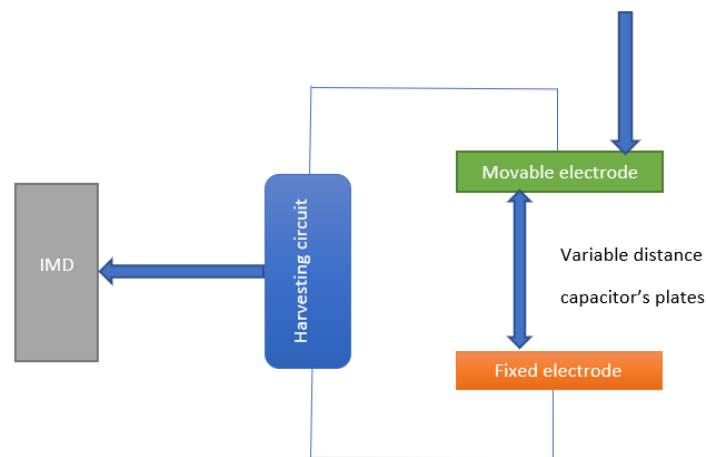


Figure 24. *Conceptual view of the electrostatic generator*

The conventional electrostatic generator is composed of two conductive plates that are electrically isolated through a capacitor or air. The distance between two plates changes due to the human's body movement. There are two methods of converting mechanical energy into electrical: with fixed potential or with a fixed charge. [46] The first type is described in figure 24 whereby movement of the plate generates a current through the capacitor - often it is called an 'electret-free' type. The second method is with a fixed charge; when an external force is applied to the structure, it causes a change in the voltage across the capacitor - sometimes this is called an 'electret-based' type. Usually, electrostatic generators are made from silicon using cutting-edge manufacturing technologies such as micromachining fabrication. This provides suitable integration capabilities with electric circuits.

The first type of electrostatic converters is electret-free, this is a passive structure that is able to transform mechanical energy into electrical energy. Charge-constrained and voltage-constrained are the conventional methods of energy conversion.

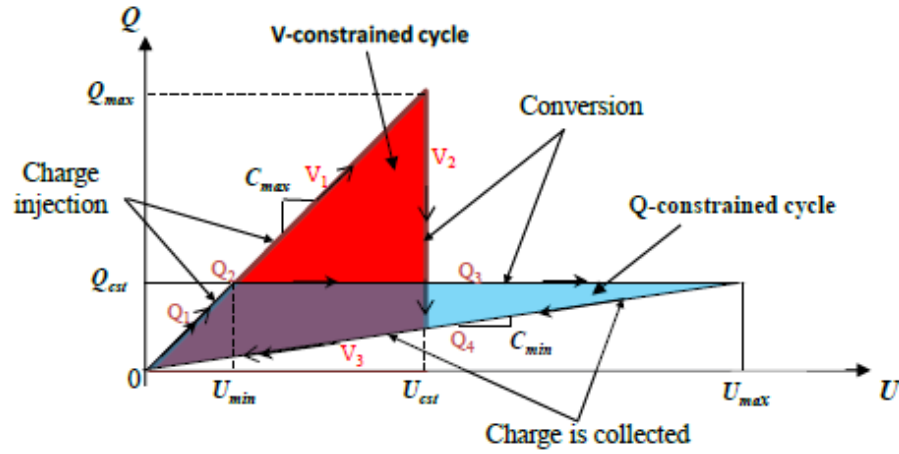


Figure 25. Energy conversion principles of electret-free electrostatic IMDs. [208]

- Charge-constrained method

The charge-constrained method is relatively easy to implement on a real design. The conversion cycle begins with the external injection of the charge, and due to polarization effect, the whole structure reaches maximum capacitance C_{\max} . At this moment capacitor C has a charge Q_{cst} under the voltage U_{\min} . Then, the circuit becomes open and the capacitance of the systems moves to the minimum level. However, the capacitor keeps charge Q_{cst} at a constant level, causing an increasing voltage across the capacitor C . When the capacitor reaches C_{\min} , electric charges are moving from the structure and feed it to the load. The total amount of energy calculated is shown in equation 17

$$E_q = \frac{1}{2} Q_{\text{cst}}^2 \left(\frac{1}{C_{\min}} - \frac{1}{C_{\max}} \right) \quad (17)$$

- Voltage-constrained method

The voltage-constrained method has the same principle at the beginning of the process, with the structure reaching maximum capacitance C_{\max} and polarized at voltage V_{cst} and C_{\max} . The main difference, in this case, that the voltage is then kept at a constant level with decreasing capacitance, causing an increase of the charge of the capacitor; this generates a current that is scavenged and stored. The next step is charge transfer to the load. The total amount of energy is calculated in equation 18

$$E_v = V_{\text{cst}}^2 (C_{\max} - C_{\min}) \quad (18)$$

The second type of electrostatic converters is the electret-based converter shown in Figure 26. This type is quite similar to electret-free structures; however, electret-based converters don't need any external energy for polarization and have a direct energy output from the deformation of the structure.

The electret-based harvester is composed of two plates with fixed and movable electrodes. According to Gauss's law, the electret induces charges on electrodes and counter-electrodes. The electric charge on the electret can be calculated as:

$$Q_e = Q_1 + Q_2 \quad (19)$$

When the structure is subjected to a mechanical stress, one of the plates moves away from the electret, changing the air gap and then the electret's influence on the counter-electrode, leading to a reorganization of charges between the electrode and the counter-electrode through load R [208].

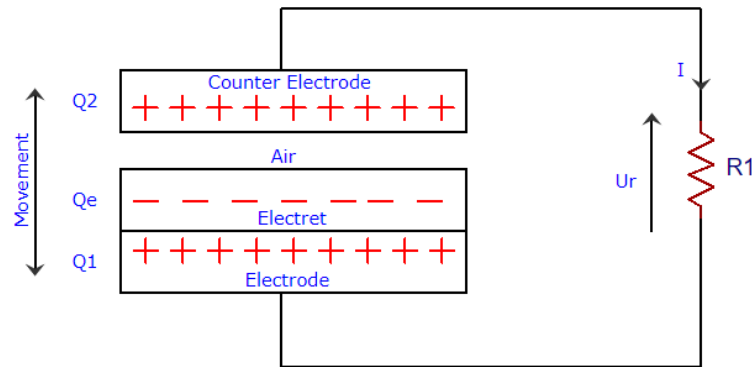


Figure 26. *Electret-based electrostatics conversion model.*

All of the electrostatic generators are based on capacitors; there are various types of capacitor structures used, such as in-plane gap closing converter (a), in-plane overlap converter (b), in-plane converter with a variable surface (d) and out-of-plane gap closing converters (c) (Figure 27).

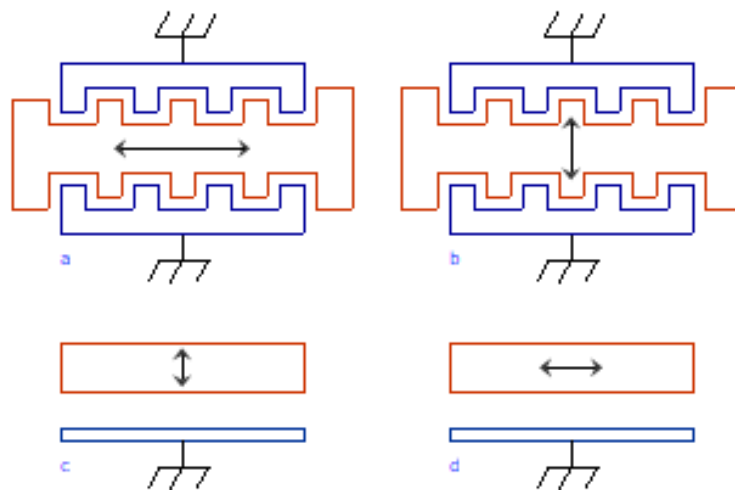


Figure 27. *Capacitor structure*

Tashiro designed an electrostatic generator which is able to provide up to 50 μW when placed in motion by a force simulating the cardiac signal. [47] Later, in 2002 he further developed this design, and his research group tested this electrostatic generator (ESG) with animals, obtaining a

heartbeat up to 190 bpm. [48] In 2006, Miao proposed a resonant less MEMS ESG for the IMDs, which produced approximately 80 μW . [49] A great variety of ESGs are available in the present time on the market [50]. Meninger [217], demonstrated the design of an electric circuit which can convert external vibrations into electricity with the use of a variable capacitor, which is applicable for low power applications. The theoretical results showed a device with relatively small dimensions - 1.5cm x 1.5cm – which can generate 8.6 mW from an excitation of 500 nm at 2.5 kHz. Furthermore, the energy output can be improved by adding an additional capacitor connected in parallel. In 2013, Deterre proposed an energy conversion method based on heartbeat vibrations. The working principle of the design is that the package of the implant is deformable, thus blood pressure effects on the electrostatic element convert vibrations into electrical power. Simulation results showed that a 25-layer electrostatic element with 6mm diameter is able to collect up to 20 μJ per heartbeat.

As a conclusion, the main drawback of this type of transducers is an additional source of energy required to operate, and usually the amount of energy which the generator produces is much smaller. On the other hand, due to dependence on the motion force, an active pre-charge system gives the opportunity to dynamically optimize the generator for the applied motion.

4.6 Electromagnetic harvesters

The principle of energy conversion is based on the electromagnetic induction when an electromotive force (EMF) is induced in a conductor moving in a magnetic field and crossing its magnetic lines of force.

$$V = -\frac{d\phi}{dt} \quad (20)$$

Where ϕ is flux linkage and V is induced EMF. Usually the generator's design is composed of coils. Therefore, the output voltage or EMF calculated as

$$V = -\frac{d\Phi}{dt} = -N \frac{d\phi}{dt} \quad (21)$$

Where Φ is the total flux linkage, N is the number of turns. Φ calculated as

$$\Phi = \sum_{i=1}^N \int_{A_i} B * dA \quad (22)$$

Where B is the magnetic field flux density over the i^{th} coil's turn.

Consequently, such a conductor can be regarded by us as a source of electrical energy. There are two types of mechanical generators that generate electrical energy. The first method is based on relative motion where the generating system is fixed, and the second method is a rigid body motion and uses the inertia force of a weight on the generator [51].

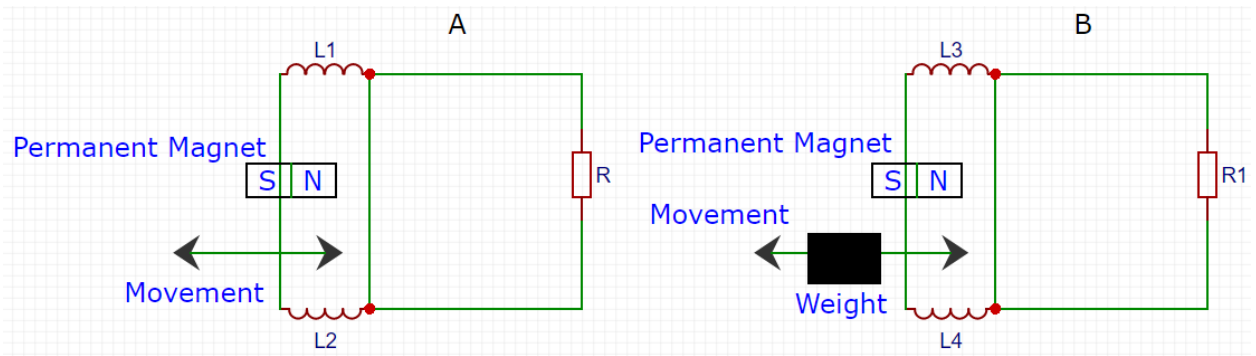


Figure 28. Types of mechanical generators: a) relative movement, b) rigid body

Typical movements of the human body can be used as a possible solution for powering biomedical sensors based on electromagnetic generators. For instance, a small electromagnetic generator can produce $400 \mu\text{W}$ from human walking [52]. As another example, the heartbeat can produce up to $200 \mu\text{W}$. [53] High-performance bulk magnets, multi-turn and macroscale coils are readily available; nevertheless, the main challenge for the MEMS fabrication technology utilized in this approach is the poor properties of planar magnets. [54]

As a conclusion, electromagnetic generators are usually less efficient and more bulky than piezoelectric generators. [124] A comparison of the three techniques in relation to different characteristics is presented in Table 4.

Table 4. Comparison of Electromagnetic, Electrostatic and Piezoelectric powering methods.

Features	Electromagnetic harvesters	Electrostatic harvesters	Piezoelectric harvesters
Energy density	Low	A decrease in the separation between the capacitor plates increases the energy density	High
Output voltage	Up to 0.1V	2-10V	2-10V
Frequency dependence	No dependence	No dependence	Highly frequency dependence
External source	No required	Required in electret-free converters	Not required
MEMS implementation	Difficult to implement in MEMS	Easy to implement in MEMS	Difficult to implement in MEMS
Drawbacks	Low efficiency in small sizes and low frequencies, ohmic loss in coils	Electrets can be used to provide the initial charge needed, parasitic capacitance losses	Materials can be expensive, poor coupling of piezo films at micro scale

4.7 Ultrasonic energy transmission

This method is one of the possible solutions of transferring energy to the implantable biomedical devices which receives a high level of attention recently [55-58]. What sets apart ultrasonic transmission from other methods is its high efficiency, safety for the human body, and stability against interference from other devices. [59] Typical ultrasonic power systems operate on frequencies above 20 kHz and need a propagation medium in order to deliver energy from TX to RX. For IMDs, ultrasound systems transfer energy through tissues to the implant, where it is converted to electrical energy through the piezoelectric transducer. The conventional design of an ultrasonic energy transmission system is shown in figure 29. The typical applications for ultrasound energy system are cochlear implants, pacemakers and neurostimulators. [146-148,150]. The system is composed of transmitter, power-system and receiver. According to the equation 23, it defines the received power, P_r :

$$P_r = \eta_{AE} I_{AC} S_A \quad (23)$$

Where η_{AE} is electric efficiency pf the receiver, P_r received power

The transmitter transforms electrical energy into mechanical energy and then acoustic energy and is composed of an ultrasonic oscillator electrically excited to generate mechanical vibrations on the surface of the TX; these vibrations cause acoustic pressure waves. The receiver has the same functions but in reverse order. [57] Based on the Huygens-Fresnel principle, each point on the transducer can be treated as an independent source of radiation, and the acoustic field pattern can be found at the vector sum of all the point-radiating sources [144]. The pressure field P at an observation point L (x, y, z) is given by the Rayleigh integral in equation 24:

$$P(x, y, z: t) = \frac{jk p_0 c_0 u_0}{2\pi} e^{i\omega t} \int_S \frac{e^{-jkR}}{R} dS \quad (24)$$

Where λ is the wavelength, ω angular frequency, k wave number, R is the distance between point source and the observation point, u_0 is the vibration velocity amplitude, c_0 phase velocity of the wave, p_0 density of the medium [165].

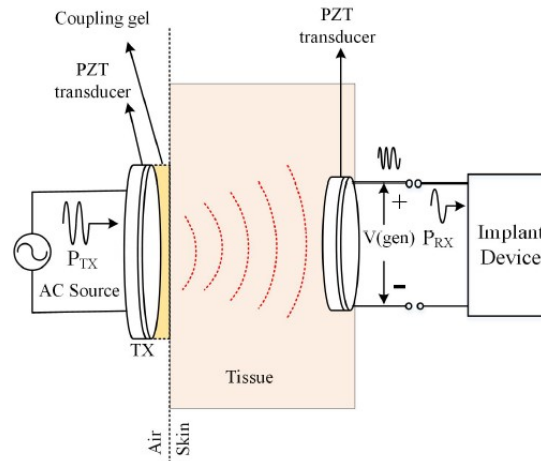


Figure 29. Schematic of ultrasonic IMD. [165]

Power transfer efficiency depends on different aspects, for instance, losses in the transducer, tissues and rectifier losses, impedance matching. Losses have a negative impact on the system performance.

Using piezoelectric components made from lead zirconate titanate have a more beneficial effect on energy efficiency conversion than piezoelectric polyvinylidene fluoride, due to different electromechanical and mechanical factors k and Q .

It is very important to choose the right operating frequency because it affects tissue attenuation, transducer thickness, the distance between the natural locus and the sizes of reactive elements in transmitter and receiver sides [165]. In order to provide sufficient quality of energy transfer, the whole system should work close to its resonance frequency. The main challenges for ultrasound transfer systems are addressed below:

The human body is complex and diverse in terms of organs and systems, each of them has different densities and acoustic impedance. For example, acoustic impedance is quite high in bones, consequently all ultrasound waves will be reflected.

Another problem is related with implants which are placed under the skin, where the spatial separation can reach several acoustic wavelengths, therefore it effects on power transfer efficiency (PTE). Another changes which affect on PTE are changes in tissues and ambient temperature [153]. Overall it leads to serial limitations on the battery life and system performance.

The first commercial ultrasound energy transmission device was developed in 1988, with an operational voltage of 10V and 2.25MHz frequency. This device generated an output power of $1.5\text{mW}/\text{cm}^2$. Ultrasonic systems are primarily used for medical imaging, for instance, ultrasonography. The typical frequency range for this application is between 3-6 MHz. In comparison, acoustic waves have lower speed than radio waves for given frequencies, therefore acoustic waves have smaller wavelengths. As an example, for the given frequency range, the usual

acoustic velocities in human tissues range from 1500-2000 m/s, the wavelengths 0.4 – 0.8 mm. Another possible design is described in [145].

In 2009, Tower proposed a design which is suitable for monitoring, it converts the energy of a surface-applied ultrasound beam to a high-frequency current [60]. Later, Zhu [61] used ultrasonic waves to harvest energy for the IMDs with 21.4 nW. In [128], a device was presented with an experimental Mbit/s ultrasonic transmission through ultrasonic phantoms, while in [129], [130] ultrasonic wireless transfer to power mm-sized implantable devices was demonstrated. The possible applications based on ultrasound powered method are described in [133-134]. Utilizing the ultrasound method for powering IMDs can push devices towards miniaturisation, due to short wavelength (1.5mm at 1MHz), and allows for greater energy efficiency [135].

The main advantage of this method is operational wavelength because long wavelengths are able to penetrate deeper into the human's body, moreover, this method is safe and effective. On the other hand, there are some drawbacks in this system, such as expensive equipment.

4.8 Photovoltaic infrared power radiation

Infrared energy transmission is another power delivery method for IMDs, such as pacemakers or brain implants. The main component of the system is a photovoltaic cell. Initially, photovoltaic cells were developed as a renewable energy source, however, after years of intensive research, these devices can be adopted as a power source for IMDs. Photovoltaic cells used in aerospace applications are able to transform up to 50% of light energy into electric power [201]. The principle of this energy conversion is based on the photovoltaic effect, where two different materials in close contact can produce an electrical voltage when the materials interact with light.

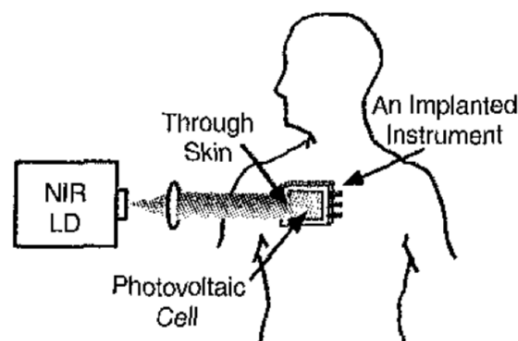


Figure 30. *Infrared power radiation system [202]*

Conventional infrared power radiation systems are composed of external light sources - for instance, lasers located on top of the skin emit light through biological tissue layers, and the light is received and transformed into electric power [214]. According to various research papers human tissues have quite a high optical transmittance coefficient in near-infrared light, hence it is possible to implement wireless powering systems for IMDs based on this infrared power radiation principle. Usually, these systems are tuned to a wavelength of about 900 nm [203]. Infrared wavelengths are able to penetrate much deeper in tissues than other wavelengths of light, but they

still suffer from various negative factors such as scattering and absorption caused by tissues [204]. Consequently, biomedical implants based on this principle typically use NIR wavelengths. In 2007 Sond and Simeral demonstrated a real design of a photovoltaic pulse neurostimulator. This system is composed of an infrared laser tuned at 852 nm wavelength and using optical fibre [205, 206].

4.9 Inductive coupling

There is another technique for delivering power wirelessly to implantable biosensors, called inductive coupling, which was first used in an artificial heart. This method is based on Faraday's law. In 1831 Faraday discovered that power could transfer wirelessly based on the principle of magnetic induction [140]. Later, power transmission over a large distance without any cables was achieved by Nicola Tesla [62]. Tesla's work was based on resonance and it was a groundbreaking achievement in that period. During the first part of 20th-century, invention and achievements were slowed down; however, due to military research, new types of high-frequency oscillators, which improve the techniques of wireless power transmission, have been developed.

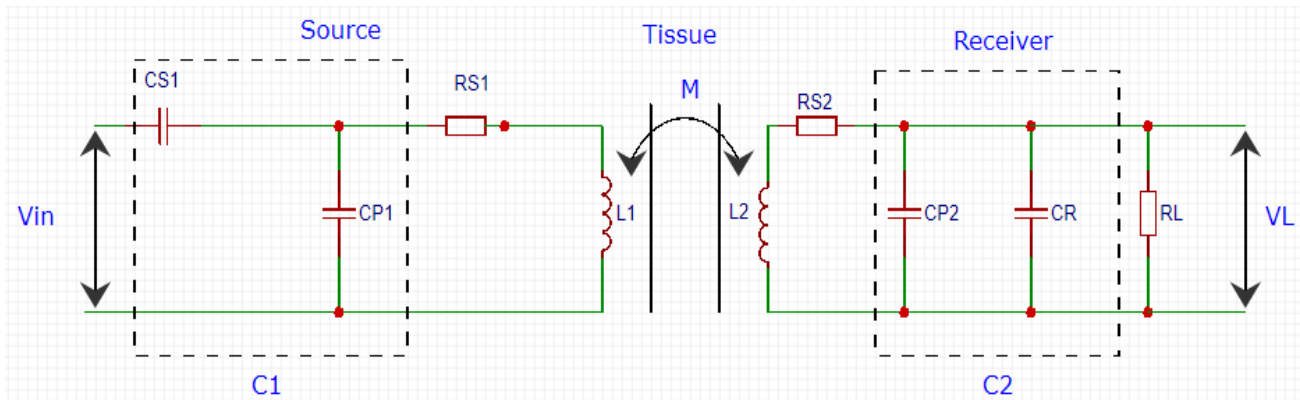


Figure 31. The architecture of Inductive coupling powering method

The NF resonant inductive coupling method is one of the most reliable wireless power transfer methods. This method has a lot of evidence that it is robust and safe for use in medical applications, as an example, it has approved results by the Food and Drug Administration (FDA).

In this method, the source part is placed under the skin surface and the receiver is placed outside. The overall design of inductive coupling scheme is illustrated by figure 31. When a voltage is applied to the primary coil, L1, it excites magnetic flux. This magnetic flux creates an EMF in the coil, L2, due to electromagnetic induction. The highest voltage is achieved when both source and receiver are tuned to the same resonant frequency, f . This frequency can be calculated by equation 25 [63-64].

$$f = \frac{1}{2\pi\sqrt{LC}} \quad (25)$$

Where L is the magnetic inductance, and C is capacitance

The transmitting and receiving coils are poorly coupled due to spatial separation. The induced EMF can be defined as

$$\varepsilon = \oint_{\partial\Sigma} \vec{E} \, d\vec{l} = -\frac{d}{dt} \int_{\Sigma} \vec{B} \, d\vec{A} \quad (26)$$

Where \vec{E} is the electric field; \vec{B} magnetic flux density; $d\vec{l}$ is the vector element of the contour $\partial\Sigma$, $d\vec{A}$ is the area vector element.

Mutual inductance is one more parameter which has a significant role in the design, as it defines the mutual inductance between two coils L1 and L2. The coupling coefficient can be calculated as [65]

$$K = \frac{M}{\sqrt{L_1 L_2}} \quad (27)$$

The efficiency of the inductive link is defined as a ratio between the power delivered to the load and the power supplied to the primary coil and is called the power transfer efficiency:

$$\eta = \frac{k^2 Q_1 Q_2}{(1 + \frac{1}{Q_2} + k^2 Q_1)(\alpha + \frac{1}{Q_2})} \quad (28)$$

$$\eta = \frac{k^2 Q_1 \alpha}{(1 + \frac{1}{Q_2} + k^2 Q_1)(\alpha + \frac{1}{Q_2})} \quad (29)$$

Where Q_1 and Q_2 are quality factors for the coils, k the coupling coefficient, α the coefficient (equal to $\omega C_2 R_L$), C_2 the capacitance of the second coil, ω the frequency, and R_L the resistance of the load. Equation 28 and 29 represent link efficiency for parallel and series resonant circuits respectively. The quality factor defines the efficiency of the inductive link.

The wireless power efficiency depends on distance, frequency and matching between L1 and L2 coils. Normally, these systems operate at a frequency of 20 MHz. There are four different schemes for how passive systems can be connected, such as series to series, parallel to parallel, series to parallel, parallel to series. These topologies are depicted on figure 32. These topologies have very poor performance under weak coupling conditions, but the series connection has better PTE than the parallel topology in strong coupling mode [141]. Both topologies provide the same amount of power to implants, however, serial topology achieves this by using high current and low voltage. On the other hand, parallel topology achieves the same result, but with high voltage and small current. [142-143] According to electromagnetic theory, rectifiers have better operational characteristics at high voltage and low current, therefore the parallel topology is more widely used for IMDs.

The number of coil turns is another important parameter. It depends on coil shape and wire properties, such as material or line size. The diameter of coils is an important parameter which affects the performance of the inductive link; increasing the diameter of the coils increases the link efficiency. In IMDs, size is a vital parameter, thus the diameter of implantable coils should be minimized, but the diameter of the external receiver coils can be larger to increase link efficiency. It is also desirable that coils are flexible, in order to be safe for the patient. [151-152].

The next important parameter is the number of turns; if we increase the number of turns in the coils, the performance of the system will be better. Another important factor is the spacing between primary and secondary coils. Therefore, the relative position of IMD and receiver play an important role. Furthermore, if the patient is moving, it can cause misalignment and interrupt the connection between transmitter and receiver.

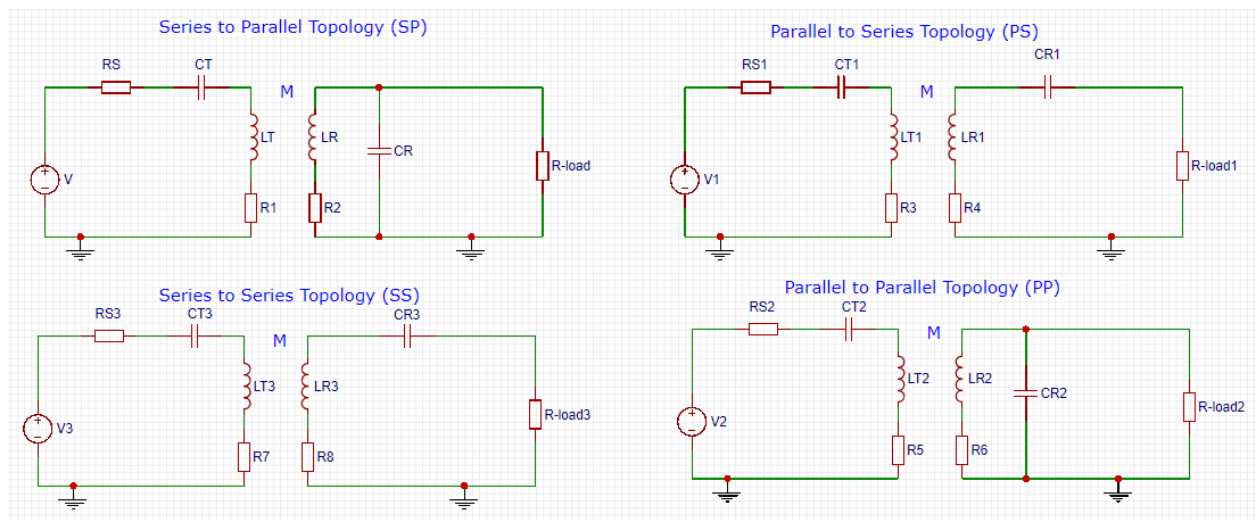


Figure 32. Types of topologies

There are many challenges in designing the optimal inductive coupling link. First of all, the IMD consumes different current at various time periods, therefore producing different loads on the scheme. However, the scheme is usually designed only for a certain load. Therefore, the link can't operate efficiently all the time. Secondly, IMDs are housed inside the human body, which moves a lot during the day, causing misalignments and artefacts becoming inherent. The inductive power link performs poorly under misalignments; in order to improve performance, new advanced designs are needed. Thirdly, TX and RX use high-quality factor coils which decrease the PTE value [156-157].

An inductive power source able to produce approximately 50mW was presented by Catrysse in 2004 [67]. This system operates at 700 kHz. Later, Ghovanloo designed a system based on SOC which can produce around 50 mW and operates at 5 MHz frequency. [66]

4.10 Far Field Communications

This type of energy transfer was also developed for powering IMDs [184]. This scheme employs the same type of antennas but tuned to different resonant frequencies than those utilized in inductive coupling. Far-field communication has certain advantages in comparison with inductive coupling, especially from a practical point of view. For example, these antennas can deliver energy to many IMDs at the same time and it is not necessary to adjust antennas accurately. As a result, the far field communication method can provide power to multiple implants located reasonably far from TX antennas; this is therefore highly suitable for implantable sensors which are located deep inside tissues. There is another advantage of using this method; it works perfectly with small antennas tuned to high-frequencies, up to several GHz. On the other hand, this configuration has a few disadvantages, for instance low power transmission efficiency in comparison with inductive coupling. This can be explained due to large attenuation at high frequencies and decreasing radiative power density at the far-field zone. Also, this technology can cause negative consequences for the human body, especially at high frequencies, due to RF absorption in tissues [185,186]. Consequently, the Federal Communication Commission (FCC) and FDA defined strict rules regarding maximum output power [187-189]. There are few examples of real applications which are based on the far-field communication principle: glaucoma monitoring devices [190], neural signal recording devices [191-192], blood monitoring systems [193], and IMDs in the ocular system [194].

4.11 Mid-Field Communication

Mid-field communication defines a range between far-field and near-field communication. This type of energy transfer was discovered in order to overcome disadvantages of far and near field communications [195-197]. Applications based on mid-field communication are able to provide various vital features, for instance recording, monitoring, and stimulating neural activities. A few years previously, a research group from Stanford University developed a mid-field wireless power transfer system which has a maximum transmission efficiency greater than far-field and near-field communication. The key component of this design is a 2 x 2 slot antenna array. By applying different RF waves in different phases on 4 ports of the antenna, optimal current density is formed, and the combination of inductive and radiative modes are generated inside the tissue [166]. Due to the deep propagation of RF waves inside the human body, focusing effects take place, causing the formation of small focal points. Hence, the mid-field communication method has one significant advantage; with use of this method, RF waves can propagate further, and with higher transfer efficiency, than inductive coupling [198]. Another example of an IMD based on mid-field communication is a miniature pacemaker. When placed deep inside of the body with a 2 mm x 3.5 mm size coil, the power output is about 2 mW [199, 200].

As a conclusion, mid-field power transfer gives an opportunity to design an electronic parts at the millimetre scale and the device can be placed nearly at any location of the body. Due to the rapid development of the semiconductors industry, these devices are able to monitor and process data equal to, or even faster than, their battery-powered counterparts. With the use of advanced

technologies such as MEMS, logic units will allow interactions with the tissue environment to be engineered. Table 5 illustrates the advantages and disadvantages of different electromagnetic power methods.

Table 5. Comparisons between different electromagnetic power methods

Type	Inductive coupling	Far-Field Communication	Mid-Field Communication
Advantages	High transfer efficiency Low tissue heating	Long transmission distance Multiple unit powering Miniature powering	Mid-field transmission Miniature powering
Disadvantages	Short range transmission Large coil size Sensitive to alignment	Low transfer efficiency Tissue heating	Tissue heating Sensitive to alignment

4.12 Bio-fuel cells

Bio-fuel cells can produce electrical energy through conversion of biomedical energy, involving chemical reactions such as oxidation and reduction. Bio-fuel cells utilize noble metal catalysts to produce electrons from fuel oxidation. An external circuit then conveys electrons to a cathode where electrons oxidize and produce energy. Figure 33 illustrates this process.

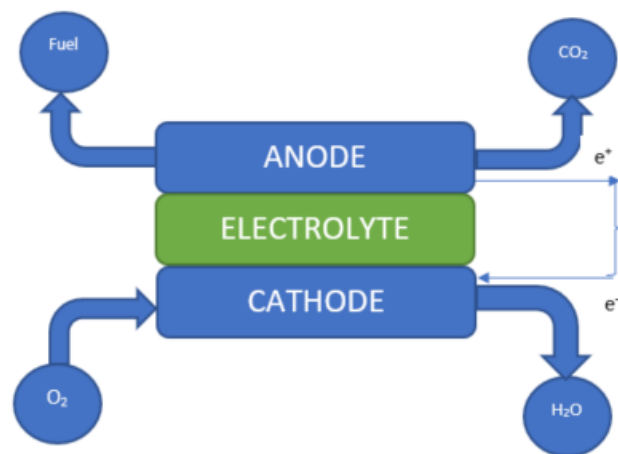


Figure 33. The design of bio-fuel IMD

Currently, bio-fuel cells based on glucose are widely used in various applications. The basic principle of these cells relies on the electrochemical reactions between oxygen and glucose. Glucose can provide up to 16 kW per gram, generating 12 electrons per molecule during the oxidation process. Relying on the metal catalyst used, bio-cells can be divided into two types: the first type is the Microbial Fuel Cell (MFC) and the second is the Enzymatic Bio-fuel Cell (EBC).

The MFC uses some microorganisms, therefore, the oxidation of the molecule of glucose cedes electrons to the bacteria. When this event occurs, the bacteria metabolism is inducted into a Redox cycle. The products of reactions in this method are water and carbon dioxide, and these components are fully compatible with the human body. However, if the device with MFC is damaged inside of the person's body, it can cause contamination of the human body by bacterial cells. The efficiency of MFC is time-dependent; according to research papers, the efficiency of MFC decreased significantly after two hours of usage with maximum values 0.0249 mA and 0.326 V.

The EBC is another type of BFC that uses enzymes as a catalyst to oxidize its fuel rather than precious metals. Enzymes are proteins that are used in chemical reactions as an intermediate link in the person's body. The two main components which participate in the enzymes reactions are substrates and products. The speed of reactions depends on the enzymes and substrates. Molecules of the enzyme are very specific, so the reaction starts only when a link between substrates and enzymes is established. The power efficiency of the BFC depends on which kinds of enzymes are in use and the size of the system. According to publications, a power density up to 1.39 mW cm^{-2} can be achieved.

The concept of bio-fuel cells (BFC) was discovered in 1911 by MC Potter, when he noticed that a culture of the bacterium *E. coli* can generate current up to 0.5mA. Later, due to development of MFC technology, a new idea of energy generation from treated biological waste has been offered. In 2003, Mano [218] published his study about a bio-fuel cell which is able to generate $2.4 \text{ }\mu\text{W}$ of power and 0.52 V.

This technology has great advantages, such as environmental friendly effects, and high efficiency and bio compatibility with the human body. Additionally, the technology has the ability to operate at temperatures between $20 - 40^\circ\text{C}$. On the other hand, there are some drawbacks still remaining. First of all, it is challenging to maintain biocatalysts over a long period of time. Secondly, the output power level is usually around few microwatts, giving limitations in some applications.

5. CURRENT CHALLENGES AND FUTURE PROSPECTIVE OF IMDs

The biomedical device manufacturing industry is one of the fastest developing industries in the world. eHealth care applications have a great opportunity for continuous monitoring. There is a great variety of medical applications which are vital for human beings; they can help to diagnose and monitor health, these include pacemakers, EMG, ECG, and brain implants. Most of these devices are battery operated. Therefore, energy management is a key issue, especially for longer durations. There are some important limitations for implantable sensors: patient safety, reliability, low power consumption, small dimensions, high data rate, and low cost. There are various factors that lead to the limitation of wireless energy distribution. First of all, it is not often possible to design and implement transmitters and receivers in a small enough size to make it suitable for a miniaturized implantable system. The second issue is the range of the energy transfer. According to the latest publications, the current systems are able to transmit energy only in a relatively small range, typically at a maximum of one meter, causing problems with real implementation. The third problem is power efficiency; usually this varies between 45% and 80% in comparison to battery or wired-based technologies. Recent studies show short summaries about the advantages, drawbacks, and power generation of different powering methods for implantable biosensors.

5.1 Power management

The wireless communication link consumes a lot of energy from the wireless implantable system. The main goal is to reduce power consumption of the RF transmitter in order to extend the lifetime of the implantable part. The FCC allocated the frequency range between 402-405 MHz for medical implant communication services (MICS), and frequency ranges between 608-614MHz, 1395-1400MHz and 1427-1432MHz for medical telemetry [215].

Batteries are the main barrier in the design of IMDs. Batteries can be classified into two types: single-use non-rechargeable and rechargeable. For instance, pacemakers and defibrillators have one-time use batteries. Insulin pumps and pacemakers have rechargeable batteries. The single-use batteries must be replaced when the output power is lower than the minimum level for device operation. That level can be monitored by wireless inductive telemetry. Single-use batteries must be changed by surgery, while rechargeable batteries can be recharged wirelessly. Telemetry systems consist of two main parts: a receiving coil, which is located inside of the body, and a transmitting power system.

The telemetric link can be used for 2-way communication or full duplex communication to transfer data such as saved health information about the patient and information about the external unit; this link also gives an opportunity for programming devices or communication between several

IMDs utilizing the same wireless link. There are various modulation techniques used for communication between IMDs and power stations. For example, AM, FM, PM, FSK, and PSK are also used for data communication; a detailed description of each of these modulation techniques can be found in chapter 3. Data transfer requirements of the IMD is the key factor for selecting modulation method. The lower operational frequencies provide low data rates and higher frequencies provide high data rates. The second factor for modulation method selection is the availability of power or bandwidth. It is very important to choose the correct modulation technique because it increases channel capacity, reduces power consumption of the transmitter, improves the quality of the signal, and enables reliable transfer of data in the presence of disturbances such as noise, deep fading, and interference [212].

There are different energy harvesting methods that have been invented, such as physical, chemical, or mechanical energy generation. This allows the IMD to get energy from natural body motion or the physiological environment wherein the IMD has been placed. Sontag proposed to use high density electroactive polymer brushes of poly-thiophene, made by means of a surface-initiated Kumada-type polycondensation reaction, to power IMDs [84]. Rapoport presented a novel design of a bio-fuel cell that produces up to 3.4 μW , which utilizes glucose oxidation. [85]

5.2 Biocompatibility

Biocompatibility of implantable devices is a vital issue. When the IMD is placed inside of the body, biological tissues react to the foreign object. Consequently, in addition to traditional invasive surgical procedures, special conditions should be also be fulfilled in order to eliminate infections before implantation, which can cause lethal consequences. For example, the probability of infection during implant installation ranges from 1%–17%. A great variety of sterilization methods exist at the present time, such as dry heat sterilisation, gas plasma sterilisation, gamma radiation sterilisation etc. To avoid blood and tissue incompatibility due to implants, these devices should be packaged within biocompatible materials, as discussed by Park [86]. Most IMDs, such as pacemakers, cochlear implants and implantable cardioverter defibrillators, are sealed by a biocompatible material. Currently, the most effective biocompatible materials are titanium and its alloys, noble metals and their alloys, biograde stainless steels, some cobalt-based alloys, alumina, zirconia, quartz, tantalum, niobium, titanium-niobium alloys, fused silica, silicon, and some biocompatible polymers [87-97].

Biofouling is a significant issue which influences how IMDs work. In fact, implantable devices will be exposed continuously to different elements of the body. After some time, bio-organisms or biomolecules within the body will interact with the surface of the IMD, reducing the functionality of the device [98,99]. In order to prevent biofouling, several methods of coating have been invented; they are added to the device package. This, however, causes an increase in the size of the device. Voskerician and Schmehl demonstrated that different types of coatings such as gold, silicon nitride, silicon dioxide, silicon carbide are able to significantly reduce biofouling.

5.3 Health issues related to wireless power transfer energy

Health risks should be taken into account at the designing stage of wireless power transfer system for IMDs. Energy radiation is able to warm up biological tissue due to the thermal effect; if this effect has a very high level, it can have a negative impact for the patient's health. In order to prevent harmful effects and regulate the usage of frequency bands, the American National Standard Institute standard dictates the electromagnetic field strength limits for frequency ranges between 300 kHz and 100 GHz. The IEEE C95.1-1991 standard regulates the electric and magnetic field strength limits for public use for the frequency range between 3 kHz-300 GHz. [100]

Table 6. IEEE C95.1-1991 Maximum electric and magnetic field strength limits for public use

Frequency Range (MHz)	Electric Field Strength, E (V/m)	Magnetic Field Strength, H (A/m)	Power Density, S (mW/cm ²)		Averaging Time E ² , H ² (minutes)
			E-field	H-field	
0.003-0.1	614	163	100	1E6	6
0.1-3	614	16.3/f	100		6
3-30	1842/f	16.3/f	900/f ²		6
30-100	61.4	16.3/f	1		6
100-300	61.4	0.163	1 f/300 10 10		6
300-3K	-	-			6
3K-15K	-	-			6
15K-300K	-	-			616000/f ^{1.2}

SAR (specific absorption rate) is an important factor which indicates the amount of RF exposure by a human. SAR is used to measure the amount of energy absorbed by a body which is exposed to an electromagnetic field. It is defined as the power absorbed per mass of the tissue, with units of W/ kg or mW/g [216].

$$SAR = \int \frac{\sigma(r)|E(r)|^2}{\rho(r)} dr \quad (30)$$

Where σ is the electrical conductivity of the sample, E is the RMS electric field and ρ is the sample density.

The normal amount of RF radiation for a human is approximately 90 MHz; therefore, standards are very strict in this case. The SAR value should have fulfilled standard requirements [101-102]. The average SAR level for the human body should be within 0.5 W/kg, as this is the main requirement according to the IEEE C95.1-199 standard [103]. The maximum SAR level permitted from cellular radiation is 1.7 W/Kg [104].

5.4 Size of the IMDs

The size of IMDs must be as small as possible. The battery usually occupies a significant proportion of the sensor. For example, smartphones are getting smaller with every new generation, whilst medical vendors are constantly striving to produce compact and user-friendly devices. The main issues with sensor batteries are their limited lifetime and the possibility of a negative effect on human health. This is why vendors now try to produce battery-less sensors and provide wireless power transfer solutions. The lithium battery is able to provide 1400-3600J/cc, and allows sensors to operate for a long period of time. Methanol based fuel cells can be more efficient than lithium batteries because they can provide up to 17.6kJ/cc. Wirelessly powered IMDs in mm- or sub-mm-sized form factors have the potential to enable advances in applications like neuromodulation, localized biosensing, and targeted drug delivery [131].

The antenna is embedded and has an impact on most implantable devices, meaning antenna design is a significant issue - due to limitations on the size, material and shape of the antenna. The propagation environment changes according to different factors, including patients' age, weight gain or loss, and posture changes [106]. Only biocompatible, high-quality materials can be used for example, platinum or titanium, which have better performance in comparison with basic copper antennas. The dimensions of an implant depend on application and location, bringing limitations in the design. For instance, the loop antenna is perfectly suitable for biomedical application, especially for implant communication applications, due to lack of dependency of permittivity. On the other hand, there are some problems if the IMD has a metal case or shield.

5.5 Frequency band selection

The carrier frequency is another vital factor in a wireless power system. There are a great variety of IMDs working on frequencies less than 1 MHz, with different applications using various frequencies, for example, RFID uses 125-135 kHz. The main reasons why vendors should use a specific ISM band are as follows: to reduce interference between other devices which utilize the same frequency band, to provide safety for human health, to improve the robustness of the communication link, and to achieve a higher throughput on the network. Deep fading occurs when a received signal is distorted due to various obstacles or interference from other devices. This can cause the inability of the wireless node to maintain uninterrupted communication with other nodes, and as a result it reduces the reliability and energy efficiency of the system. Interference control and mitigation methods for deep fading are especially significant for medical applications, where uninterrupted communication is required. The interference problem - which can appear from in-body, on-body and off-body communication links - can be solved by using different types of diversity, for example 'channel' or 'antenna' diversity. This issue becomes challenging if the signals are able to attenuate, or become distorted, in or around a human body; the effects depend on the body size, volume of muscles, and any body movement.

5.6 Antennas

The antenna is an important part of the implantable sensor, and for its radio link communication. Antennas for medical applications should meet certain requirements such as radiation efficiency, operating bandwidth, patient safety, and size. Body wireless communications systems (BWCS) is a very prospective type of future communications. BWSC are composed of three types of communication: on-body, in-body, and off-body. The first type defines communication between various wearable devices. The second type means communication with external networks. The third type can be defined as communication to an IMD or sensor.

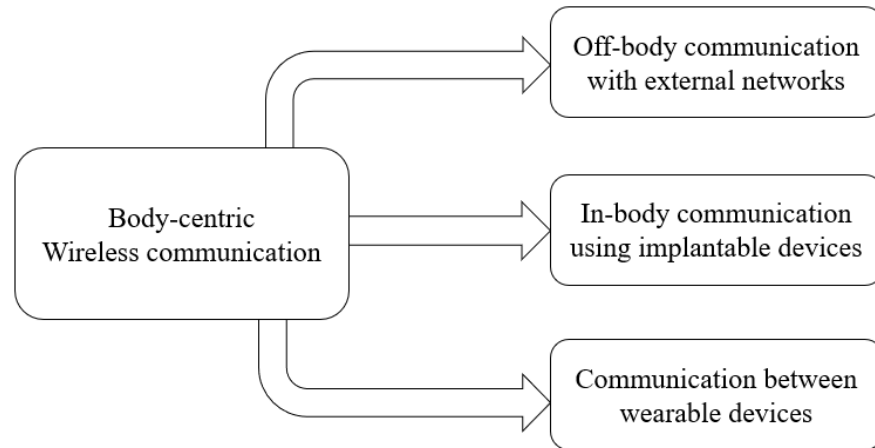


Figure 34. Types of body wireless communication

Recent research publications for implantable antenna design:

5.6.1 Dual-band operation antenna

The main principle of dual-band antennas, is a switching between two modes - wake-up, and sleep - thus saving energy and extending the lifetime of the battery. Usually, dual-band implantable systems operate in the sleeping mode in the ISM band and change to the MICS band only in wake-up mode. In 2008, Karacolak [69] designed a miniature DBIA which operates in ISM and MICS bands for continuous glucose-monitoring applications. Later, in 2010, Sanchez-Fernandez [70] introduced a novel dual-band micro-strip patch antenna for two bands MICS (402-405 MHz) and ISM (2.4-2.48 GHz). In 2014, Zhu Duan [71] designed a new differentially dual band antenna which operates at MICS and ISM bands; the antennas are made from a parylene-c material, with a tiny flexible case of 179.0 mm³ and 186.3 mm³ respectively. Characteristics of the communication system between an external half-wavelength dipole and implanted antennas at two resonant frequencies presented in [126]. Another different approach can be found in [72-75]. In 2017 H. Behvar proposed novel dual port planar antenna for inductively coupled IMDs. This antenna utilizes two circularly polarized implantable antennas.

It is well known that wireless communications suffer from multipath propagation, due to various obstacles, movement of people, weather conditions, and other effects. For these cases, an implantable circularly polarized antenna is desired. Real-life examples of these can be found in

[76-78]. The circularly polarized patch antenna was designed for 2.4-2.48 GHz band, with $10 \times 10 \times 1.27$ mm³ dimensions. The simulated and measured impedance bandwidths in cubic skin phantom are 7.7% and 10.2%. Another example of a circularly polarized antenna design was published in 2015 by Li-Jie Xu [79]. That circularly polarized antenna operates in the 902-928 MHz ISM band. Right and left-hand polarization can be implemented, depending on the positions of feed and shorts. The dimensions of that antenna are $13 \times 13 \times 1.27$ mm. The simulated results show that a wide bandwidth of 18.2% can be realized with $|S_{11}|$ below -10 dB and an axial ratio below 3 dB. The simulated realized gain is -32 dBi at 915 MHz.

5.6.2 Implantable antennas for wireless power transfer

There are two types of batteries used to power IMDs: single-use and rechargeable. The main drawback for the single-use battery is that of its replacement, usually requiring surgery, for example pacemaker batteries. However, wireless power transfer can help to recharge batteries for different IMDs without surgery. Implantable antennas were designed for wireless data telemetry and play a key role in near/middle/far-field power transfer. Various types of implantable antennas were studied for wireless transfer in [81,82]. As an example, in 2011 Fu-Jhuan Huang [81] implemented an implantable antenna that perfectly operates at three bands, including MICS and ISM bands, by utilizing an antenna with a specific shape. That radiator has a very small size of $10 \times 10 \times 10 \times 2.54$ mm.

5.6.3 Integrated implantable antennas

One of the key requirements for an implantable antenna is small size, especially in the case where the implant should be placed in the head or eyes. With the advent of CMOS technology, this problem has been solved. CMOS technology helps to reduce the antenna size and achieve high integration of the whole implantable system. The first separate transmission and reception using on-chip antennas in eye environment for intraocular pressure application was designed by L. Marnat in 2012 [82]. These small antennas fit on a 1.4-mm 3 CMOS (0.18 μ m) chip in addition to the rest of the circuitry.

5.7 Security

Secure communication is one of the most critical issues for various IMDs, and consequently a great variety of studies have already been presented in the literature on this topic. Some of the security challenges conflict with basic IMD requirements. Firstly, on battery life; for IMDs the duration of battery life should last for many years inside a patient's body, however, security algorithms consume an additional amount of energy, thus degrading battery life. The second issue is that of adaptability. In order to provide high-level security for various IMDs, adaptable methods that do not require any modification of IMDs are significant. Thirdly, availability; the main purpose of authentication algorithms is to prevent of unauthorized access to the IMD. On the other hand, in the case of emergency situations, when the patient is unable to turn off authentication system, the IMD should be available to a doctor for a treatment, even if he or she were not

previously authorized. Another challenge in IMD security is reliability. Security mechanisms introduce additional complexity into the system, increasing the susceptibility of IMDs to software bugs and hardware impairments that lead to malfunctions. Therefore, security algorithms should be robust and provide high-level reliability.

Most of the security techniques in wireless communication based on cryptography are used for impersonation and eavesdropping [113]. However, most of the common security approaches may not be suitable for IMDs. For instance, secret key storage and data encryption are memory demanding operations [112] which might be a problem for the proper deployment of IMDs, because they have limited memory. For example, in [110] and [11], authentication is implemented based on a friendly jamming algorithm. When the Guardian detects a spoofing attack by adversaries attempting to hide their existence from Guardian and gain access to the IMD, Guardian activates a defensive jamming mechanism to notify the IMD about the threat. Note that, this protocol requires a collaboration with the IMD and Guardian. Moreover, encryption with stored and pre-shared keys conflicts with accessibility requirements of IMDs, for example in the emergency case when a doctor should be able to have access in order to treat patients, even if he or she were not previously authorized. One of the possible solutions to overcome these challenges was introduced by [114], suggesting the use of psychological signals. In practice, this is used for electro-cardiogram (ECG) and photoplethysmogram (PPG) signals in [115]. Another possible solution is where inter-pulse intervals (IPIs) of heartbeats are exploited to generate security keys in [116]. The ECG based security key generation has a lot of advantages in comparison with other methods in the literature [110], because of higher randomness as compared to other physiological signals, such as blood pressure, heartbeat, and temperature. The randomness of physiological signals (PVs) is still an open question for practical scenarios [117].

For security communication control between the IMD and the programmer, and considering the accessibility requirements, Denning discussed the usage of wearable external devices [119] and introduced Cloakers [118] as a new direction in IMD security. Another popular trend for preventing spoofing attacks is anomaly detection-based authentication; this method observes the IMD related activities, either in the body or between transceivers, to understand the legitimacy of incoming commands. Anomaly detection-based methods in [120,121] use the changing patterns of different parameters [122], such as time of arrival and received signal strength (RSS).

All of the security methods mentioned above should be evaluated according to the most significant threats. In eavesdropping resistant methods, PV based methods have some important advantages in comparison with common cryptography methods, such as accessibility and availability, but they suffer from low randomness and noisy measurements. However, in [123], researchers cope with these problems, but still have disadvantages against intelligent attackers, as presented in [124] which contributes modifications in IMD algorithms. A friendly jamming-based method in [111] provides protection for IMDs without the issues mentioned above. In addition, this method is more power efficient due to all security activities undertaken by an external device. PV-based key generation may be more convenient for authentication, but less effective for secrecy against

eavesdroppers as it is a real-time operation and does not exhibit high entropy. However, there are also other issues relating to authentication which should be considered.

Table 7. *Current trends addressing various threats to IMD security*

Methods	Eavesdropping	Impersonation	Jamming
Cryptography (Regular or PV-based)	+	+	-
Anomaly detection	-	+	-
External device deployment	+	+	-
FHSS and DSSS	+	+	+

Maintaining security against different types of attacks for communication with IMDs is still an open problem, with researchers globally trying to find effective solutions.

5.8 Amplifiers for IMDs

The power amplifier is one of the main components in an implantable device, and it defines the efficiency of the system. There are currently several different types of amplifiers in existence and used in present applications. The ‘A class’ is the best class, with low signal distortion and high linearity. The ‘B’ and ‘C’ classes operate with the same principles and properties but with lesser quality. The most popular classes of amplifiers for IMDs are ‘E’ and ‘F’. The ‘E’ class amplifier requires only one active device, and as a result has a shifting resonance frequency and a decrease in the output power. On the other hand, ‘F’ class usually utilizes two devices at the same time, causing an increase in power consumption and an increase in the dimensions of the system.

Table 8. *Comparisons between different power approaches*

Energy powering methods	Advantages	Drawbacks	Generated power
Thermoelectricity	Long life-time	Low output power	5.8 μ W 1 μ W 180 μ W/cm ²
Piezoelectricity	High output voltages High capacitance	Expensive components Coupling coefficient linked to material properties	1W 0.33 μ W 2.1-69.8W
Electromagnetic	High output currents Long life	Low output voltages Expensive components Low efficiency	40-200 μ W 1.1mW 400 μ W
Electrostatic	High output voltages Low cost materials	Low capacities	36 μ W 58 μ W

		No direct mechanical to electrical conversion	80 μ W
Bio-fuel cells	Environmentally friendly Biocompatibility with human body	Short life-time Low output power	2.4 μ W
Ultrasonic	Data transfer May be used for different depths	Low output power Side effects	1.5mW/cm ²
Inductive coupling	High data rates No batteries needed	Limited carrier frequency due to tissue absorptions Side effect	19mW 150mW 50mW 6.15mW
Lithium batteries	Compatible with flexible electronics	Size, Toxicity	210 W*h/kg

5.9 Future prospects

With the fast development of cutting-edge technologies, the medical industry has changed a lot in many aspects. There has been a transformation in the traditional way of diagnosis and monitoring of various diseases and their prevention in the early stages. Moreover, the roles of doctors and nurses have changed as patients are now able to monitor their health status with cutting edge technologies within e-care, IoT, and mobile health. These technologies provide continuous diagnosis and can transmit data to doctors who can be located a hundred kilometres away. According to figure 35, depicting a future scenario, power is needed not only for powering the IMD, but also for maintaining the wireless communication link; as a result, the lifetime of the battery is reduced.

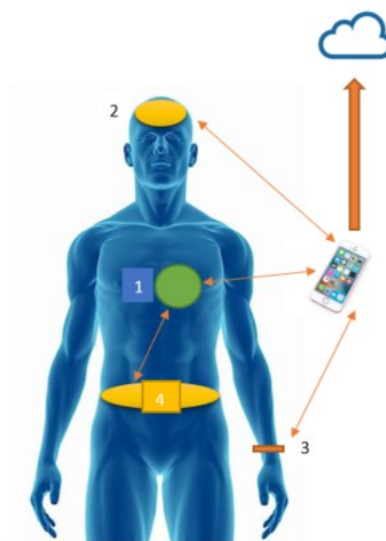


Figure 35. Overview of the future system

According to this scenario, an implantable device is powered by an external device, for instance, a wearable belt. Simple, robust and affordable implantable sensors hold great promise for various types of medical procedures. The design of small wireless sensors, such that they fit easily into an implant or sensors, is an important factor for the real-time measurement of various health parameters. For instance, future research may include utilizing multiple sensors in a multi-axial load cell to monitor in-vivo loading in the spine in real time.

Energy efficient hardware should always be employed in IMDs; existing wireless technologies have a high current peak and mostly use duty cycling between standby and active modes in order to reduce the average current drawn. Cutting-edge technologies in the hardware for sensing technologies can minimize the peak current drawn [106]. Thus, devices can work on low low-peak currents. These cutting-edge technologies are wake-up radios [107] and low-power listening devices [108], which are able to reduce power consumption by standby listening. Crystal is one of the costly, heavy, and power demanding components of the sensor, therefore inventing the crystal-less radio [109] is one possibility to reduce dimensions, price, and power consumption of the IMD. For wireless transmission, IMDs can transmit information to a smartphone. Different types of algorithms can be implemented for filtering and sorting information for doctors or storage in healthcare centres. Fast data processing and storage space are the main requirements for future IMD systems; cloud-based systems are feasible solutions for these criteria. Future systems will help to improve the quality of life for patients, save time for diagnostics, reduce expenses, and increase the efficiency of treatment. In the next few decades, miniaturization of IMDs is expected, because this allows close proximity to the organ and the ability to treat the target directly. Wireless powered implants will have a decisive advantage, due to their lack of connecting leads - the weakest part of a basic implant.

6. CONCLUSIONS

Life becomes more pleasant with good health. The invention of IMDs has extremely improved a patient's quality of life. This work summarises the various harvesting methods which can be used for powering wireless IMDs; their characteristics, current challenges, and future vision. On the one hand, there are different battery-based methods (battery, thermoelectricity, electrostatic methods), on the other hand, there exist wireless power transmission methods (magnetic coupling, ultrasound methods). The goal of the research has been successfully achieved. The main challenges for wireless implants are biocompatibility, security and lifetime of the batteries. However, in order to solve problems with the delivery of power to the IMD, various approaches have been developed to replace battery-based systems for powering implants. The independent system method employs the body's energy, for instance, everyday human activity such as walking, jogging or breathing, body temperature to produce electrical energy for harvesting for the IMD. These methods are based on electromagnetic, thermoelectric, and electrostatic principles, however, these methods suffer from various challenges, such as low output power and limited implant location choices. Systems with an external unit - operating based on inductive coupling, optical charging, or the ultrasonic transmission - provide great possibilities for transferring data and energy simultaneously. All these methods have advantages and disadvantages. Hybrid systems such as [154-155] can improve the quality of energy transfer. According to research, energy transfer by wireless resonant magnetic coupling is the most highly regarded technique for supplying implants. Nevertheless, this method still has limitations. For a secure wireless power transfer (WPT), the skin should not be exposed to an energy density higher than 10mW/cm^2 , which is established by ANSI. Resonant coupling WPT is a method that can be technically improved in order to satisfy an implants' energetic needs with respect for the international limits of magnetic field exposure to the human body. Moreover, different modulation techniques, their principles, and their characteristics have been reviewed. FSK modulation is the most suitable approach for digital transmission, for instance, whilst PSK modulation is now widely used for implantable wireless devices, employing a coupling inductive link to transmit both data and power. The main challenges in wireless power and data transmission are data rate, power consumption, modulation technique, and operating frequency. Consequently, choosing the most suitable modulation technique is very important to achieve targeted data rates and power consumption of the system. In order to fulfill the aforementioned requirements, advanced technologies should be applied; for instance, artificial intelligence can be used to provide sufficient data rates and a stable RF signal, offering great opportunities for flexibility in updating the data to the IMD, and in automatic frequency control applications.

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